

EXHIBIT B

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

JO HUSKEY AND ALLAN HUSKEY, :
Plaintiffs, : CASE NUMBER
v. : 2:12-cv-05201
ETHICON, INC., ET AL., :
Defendants. :

TRANSCRIPT OF TRIAL - DAY FIVE

AUGUST 28, 2014

BEFORE THE HONORABLE JOSEPH R. GOODWIN,
UNITED STATES DISTRICT JUDGE

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<p>1 APPEARANCES 2 FOR THE PLAINTIFFS: 3 4 EDWARD A. WALLACE, ESQUIRE 5 MARK R. MILLER, ESQUIRE Wexler Wallace 6 55 West Monroe Street, Suite 3300 Chicago, IL 60603 7 8 FIDELMA L. FITZPATRICK, ESQUIRE Motley Rice 321 South Main Street, Suite 200 9 Providence, RI 02903 10 JEFFREY M. KUNTZ, ESQUIRE Wagstaff & Cartmell 11 4740 Grand Avenue, Suite 300 Kansas City, MO 64112 12 13 FOR THE DEFENDANTS: 14 15 CHRISTY D. JONES, ESQUIRE Butler, Snow, O'Mara, Stevens & Cannada, PLLC 1020 Highland Colony Parkway, Suite 1400 16 Ridgeland, MS 39157 17 DAVID B. THOMAS, ESQUIRE PHILIP J. COMBS, ESQUIRE 18 Thomas Combs & Spann PO Box 3824 19 Charleston, WV 25338-3824 20 21 22 23 24 25</p>	<p>Page 2</p> <p>1 PROCEEDINGS had before The Honorable Joseph R. Goodwin, 2 Judge, United States District Court, Southern District of West 3 Virginia, in Charleston, West Virginia, on August 28, 2014, at 4 8:36 a.m., as follows: 5 THE COURT SERVICES OFFICER: All rise. 6 THE COURT: Good morning. Do I have enough lawyers 7 for a quorum? 8 MS. FITZPATRICK: Something like that, Your Honor, if 9 that's what you call it. 10 MS. JONES: I apologize, Your Honor. 11 THE COURT: That's quite all right. Good morning. 12 I understand that we have an issue regarding Dr. Erin 13 Carey. 14 MS. FITZPATRICK: That's correct, Your Honor. If you 15 will recall, Dr. Carey was the expert who had -- well, let me 16 back up. 17 The defendants submitted an independent medical exam. 18 THE COURT: I remember the briefing and the 19 discussion. 20 MS. FITZPATRICK: Correct. So she was the one who 21 looked at the independent medical examination and put it in 22 her report. We have her here, coming here to Charleston, and 23 expect to put her on in our case-in-chief. We were not 24 anticipating asking her any questions specifically about 25 Dr. Pramudji's deposition but were intending to ask her about</p>																																																																																								
<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p> <p style="text-align: center;">I N D E X</p> <p style="text-align: center;">Direct Cross Redirect Recross</p> <p>WITNESSES FOR THE PLAINTIFFS</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">JO BETH HUSKEY</td> <td style="width: 10%;">19</td> <td style="width: 10%;">69</td> <td style="width: 10%;">97</td> </tr> <tr> <td>JERRY BLAIVAS, M.D.</td> <td>106</td> <td>224</td> <td></td> </tr> <tr> <td colspan="4"> EXHIBITS Ident. Evid.</td> </tr> <tr> <td>P-90017</td> <td colspan="3">20</td> </tr> <tr> <td>P-90016</td> <td colspan="3">23</td> </tr> <tr> <td>P-90019</td> <td colspan="3">29</td> </tr> <tr> <td>P-90020</td> <td colspan="3">33</td> </tr> <tr> <td>P-588</td> <td colspan="3">43</td> </tr> <tr> <td>P-91407C</td> <td style="text-align: center;">X</td> <td colspan="2"></td> </tr> <tr> <td>D-10029</td> <td style="text-align: center;">X</td> <td colspan="2"></td> </tr> <tr> <td>P-91405B</td> <td colspan="3">105</td> </tr> <tr> <td>P-90001</td> <td colspan="3">107</td> </tr> <tr> <td>P-90001A</td> <td colspan="3">149</td> </tr> <tr> <td>P-20176</td> <td colspan="3">158</td> </tr> <tr> <td>P-20178</td> <td style="text-align: center;">X</td> <td colspan="2"></td> </tr> <tr> <td>P-20180</td> <td colspan="3">170</td> </tr> <tr> <td>P-21420</td> <td colspan="3">188</td> </tr> <tr> <td>P-21379</td> <td colspan="3">190</td> </tr> <tr> <td>P-21433</td> <td colspan="3">192</td> </tr> <tr> <td>P-20015</td> <td style="text-align: center;">X</td> <td colspan="2"></td> </tr> <tr> <td>D-23591</td> <td colspan="3">234</td> </tr> <tr> <td>D-23605</td> <td colspan="3">242</td> </tr> </table>	JO BETH HUSKEY	19	69	97	JERRY BLAIVAS, M.D.	106	224		 EXHIBITS Ident. Evid.				P-90017	20			P-90016	23			P-90019	29			P-90020	33			P-588	43			P-91407C	X			D-10029	X			P-91405B	105			P-90001	107			P-90001A	149			P-20176	158			P-20178	X			P-20180	170			P-21420	188			P-21379	190			P-21433	192			P-20015	X			D-23591	234			D-23605	242			<p>Page 3</p> <p>1 the issues that she had opined in her report which relate to 2 the written independent medical examination that Dr. Pramudji 3 had done in this case, about the findings and the conclusions 4 that she had reached, specifically, with the care and 5 management of the pain syndromes from now and into the future. 6 And there's dispute significantly between the parties as to 7 both the cause of those as well as the care that Mrs. Huskey 8 is receiving for that. 9 We believe that that's appropriate, and not only 10 appropriate, but an efficient way to deal with it in our 11 case-in-chief by having Dr. Carey here to offer that testimony 12 now. 13 It's my understanding that defendants are taking the 14 position that Dr. Carey cannot testify in our case-in-chief 15 because she is a rebuttal witness to Dr. Pramudji, and, 16 therefore, we should be sending her home and bringing her back 17 next week after Dr. Pramudji has offered her opinions on the 18 stand. 19 And I think that there's a difference between a 20 rebuttal witness at trial and a expert witness that you bring 21 in during the discovery process and during the workup of a 22 case who rebuts a late-submitted expert report that came from 23 defendant, which is the reality of what happened with the 24 independent medical examination from Dr. Pramudji. 25 Dr. Carey has fully prepared a report. She has been</p>
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<p style="text-align: center;">Page 6</p> <p>1 deposed about the report. The parties know exactly what --</p> <p>2 THE COURT: Tell me what she's going to say.</p> <p>3 MS. FITZPATRICK: What she's going to say --</p> <p>4 actually, Your Honor, you limited, to a certain extent, her</p> <p>5 testimony, but she's going to come in --</p> <p>6 THE COURT: I basically -- I basically said the</p> <p>7 reason I was going to allow this late witness was because of</p> <p>8 the late supplemental report from Pramudji.</p> <p>9 MS. FITZPATRICK: That's correct, Your Honor.</p> <p>10 THE COURT: And that I would allow this witness to</p> <p>11 rebut the new matters brought up by Dr. Pramudji. Is that a</p> <p>12 fair summary?</p> <p>13 MS. FITZPATRICK: That is -- that is a fair summary,</p> <p>14 Your Honor, and it specifically deals with, I think, primarily</p> <p>15 two issues: The cause of the pelvic pain and the alternate</p> <p>16 causes that you saw in opening that the defendants have</p> <p>17 raised, and that Dr. Pramudji opines on in her independent</p> <p>18 medical examination, as well as the prognosis for Mrs. Huskey</p> <p>19 going out into the future for her medical management, not</p> <p>20 surgical management, but for the medical management of the</p> <p>21 pain conditions that she currently has going out into the</p> <p>22 future, whether those are permanent, whether they're not</p> <p>23 permanent, whether there's treatment that's available to cure</p> <p>24 them or not.</p> <p>25 And there is a discrepancy between Dr. Pramudji and</p>	<p style="text-align: center;">Page 8</p> <p>1 expert, and talk about Dr. Pramudji before she even takes the</p> <p>2 stand. And I think the Court properly ruled before that she</p> <p>3 is a rebuttal witness, if anything.</p> <p>4 We have represented Dr. Pramudji may take the stand.</p> <p>5 Things change, Your Honor. What if Dr. Pramudji doesn't take</p> <p>6 the stand? What if we decide that the cross-examination of</p> <p>7 plaintiffs' experts are sufficient in our judgment that she</p> <p>8 doesn't need to take the stand? Then you have a witness</p> <p>9 talking about a witness who doesn't appear.</p> <p>10 MS. FITZPATRICK: Your Honor, we had asked very</p> <p>11 specifically and definitively whether Dr. Pramudji was coming</p> <p>12 to trial and were told that she was coming to trial. If there</p> <p>13 has been a change, we need to know about that.</p> <p>14 But the reality is, Your Honor, in the interests of</p> <p>15 efficiency, Dr. Carey is on her way here, in the interest</p> <p>16 of -- if you'll recall, during opening, there were</p> <p>17 representations that were made by defendants very specifically</p> <p>18 about these issues and what the jury would and would not see</p> <p>19 from the medical records on these particular issues. And we</p> <p>20 just believe that it's the appropriate time to put it in in</p> <p>21 our case-in-chief. She's probably not more than an hour-long</p> <p>22 witness at most. It's relevant information to the jury, and</p> <p>23 it's information that the defendants have made very relevant</p> <p>24 to this case with their opening statements here.</p> <p>25 THE COURT: Okay. I think I understand your</p>
<p style="text-align: center;">Page 7</p> <p>1 Dr. Carey -- discrepancy is probably a kind word for it -- on</p> <p>2 that particular issue which we feel is relevant to -- for very</p> <p>3 obvious reasons, to both our case-in-chief as well as what we</p> <p>4 know is going to come in from the defendants' case because</p> <p>5 they have represented that Dr. Pramudji will be taking the</p> <p>6 stand here.</p> <p>7 MR. THOMAS: Thank you, Your Honor. David Thomas for</p> <p>8 the defendants.</p> <p>9 May I approach briefly?</p> <p>10 THE COURT: Yes.</p> <p>11 MR. THOMAS: I want to give a copy of the Court's</p> <p>12 order on this topic which --</p> <p>13 THE COURT: I don't need that.</p> <p>14 MR. THOMAS: Okay. Your Honor, the defendants moved</p> <p>15 and the Court granted a motion in limine with respect to</p> <p>16 Dr. Pramudji -- excuse me -- with respect to Dr. Carey to</p> <p>17 limit the, quote, (b)(2) opinions with Dr. Steege, granted the</p> <p>18 plaintiffs' request to submit a rebuttal report of Dr. Carey,</p> <p>19 and the Court's order is very clear, at Page 9, that Dr. Carey</p> <p>20 will not be permitted to testify about matters that plaintiffs</p> <p>21 speculate Dr. Pramudji might say.</p> <p>22 That's exactly what we have at issue here, Your</p> <p>23 Honor, is the plaintiffs are trying to preempt or anticipate</p> <p>24 what Dr. Pramudji may say about an independent medical</p> <p>25 examination she conducted in connection with litigation as an</p>	<p style="text-align: center;">Page 9</p> <p>1 argument.</p> <p>2 The Court's ruling was that this witness could be</p> <p>3 offered to rebut the testimony of Dr. Blaivas which would put</p> <p>4 her into the rebuttal phase of the case.</p> <p>5 Two options: One, I will direct that you be</p> <p>6 permitted to take her deposition in the middle of the night or</p> <p>7 whenever you have time and have it available and ready to play</p> <p>8 in the rebuttal section. Or she may be allowed to testify out</p> <p>9 of turn after the defendants open their case -- and this</p> <p>10 option would only be with the agreement of the defendants --</p> <p>11 after they have started their case and Dr. Blaivas has</p> <p>12 testified. And I have no idea when they plan to call Dr. --</p> <p>13 Dr. Pramudji. I'm getting those names wrong.</p> <p>14 But, at a minimum, because I believe that the</p> <p>15 interests of justice is best allowed by allowing the jury to</p> <p>16 hear everything that was permitted by the Court, and since</p> <p>17 these multidistrict litigations present very special problems</p> <p>18 with regard to the access to witnesses, I will allow the</p> <p>19 testimony, and I will allow you to schedule, at your</p> <p>20 convenience -- and they've got plenty of lawyers that can work</p> <p>21 it out -- to take the deposition while she's in town, or</p> <p>22 somewhere else, and use it as rebuttal.</p> <p>23 I will deny your motion to offer her as a witness in</p> <p>24 chief since I've limited it to rebuttal.</p> <p>25 MS. FITZPATRICK: Thank you, Your Honor.</p>

<p style="text-align: center;">Page 10</p> <p>1 I'm wondering if -- because I'll have to consult with 2 Dr. Carey to see if she is available to return, I'm wondering 3 when we will have some idea of what -- what day I can tell her 4 to be here for a rebuttal and --</p> <p>5 THE COURT: Let's go to that next.</p> <p>6 MS. FITZPATRICK: Okay. Thank you, Your Honor.</p> <p>7 THE COURT: As I understand it, the plaintiffs 8 anticipate that they may finish up today, and particularly 9 with Dr. Carey not being called. Is that correct?</p> <p>10 MR. WALLACE: That would be accurate, Your Honor.</p> <p>11 THE COURT: What time?</p> <p>12 MR. WALLACE: Depending on the cross-examination, 13 probably mid to later afternoon.</p> <p>14 THE COURT: Mid to late afternoon?</p> <p>15 MR. WALLACE: Yes. We anticipate that both Jo Huskey 16 and Dr. Blaivas may be on the stand for awhile.</p> <p>17 THE COURT: What's your estimate on that, Ms. Jones?</p> <p>18 MS. JONES: I'm sorry, Your Honor. I didn't --</p> <p>19 THE COURT: What's your estimate on the completion of 20 their case, since you'll have some idea of the 21 cross-examination?</p> <p>22 MS. JONES: I would guess mid-afternoon, Your Honor.</p> <p>23 THE COURT: Mid-afternoon? Are you ready to open 24 your case with a witness?</p> <p>25 MS. JONES: This afternoon?</p>	<p style="text-align: center;">Page 12</p> <p>1 (Discussion held off the record.)</p> <p>2 THE COURT: Mr. Wallace?</p> <p>3 MR. WALLACE: One issue that I think we can dispense 4 of, hopefully real quickly, Christy, I don't know if you know, 5 but we asked for a stipulation on the medical record. Under 6 Illinois law, if they're paid, they're <i>prima facie</i> reasonable, 7 so there's no necessity to go through bill by bill with the 8 plaintiff or anyone else. I was just hoping we could just 9 have a stipulation on that. It's a real simple --</p> <p>10 MS. JONES: We have no intention, Your Honor, of not 11 stipulating as to the reasonableness of what has been paid. 12 There may be a question as to whether or not some of the 13 medical records relate directly to Ms. Huskey's treatment 14 relating to this, but we'll just -- I've not seen that. I 15 know that we raised that earlier and with that --</p> <p>16 THE COURT: So the kind of witness he's trying to 17 avoid can be avoided?</p> <p>18 MS. JONES: I understand.</p> <p>19 MR. WALLACE: And, Your Honor, they have those, those 20 documents, and I just don't want to close our case without 21 that being understood, that --</p> <p>22 THE COURT: Okay. Well, I think I understand the 23 position of both parties. We're not going -- we're not going 24 to, for the sake of form, call records custodians.</p> <p>25 MR. WALLACE: And the plaintiff herself, under</p>
<p style="text-align: center;">Page 11</p> <p>1 THE COURT: Yes.</p> <p>2 MS. JONES: I suppose we could with a video, Your 3 Honor. In all candor, we were anticipating it being tomorrow, 4 based upon our conversations, but I think we can do it if we 5 need to.</p> <p>6 THE COURT: All right. It's not fair to waste a 7 half -- I know the conversations that went on yesterday. It's 8 not fair to waste a half a day of the jury's time. If we 9 are -- if we're creating, as I am, a hole in time, I'll blame 10 it on the plaintiffs who are creating a hole in time.</p> <p>11 MS. FITZPATRICK: Oh, Your Honor, you're killing us. 12 Jeez.</p> <p>13 (Laughter.)</p> <p>14 MS. FITZPATRICK: Okay.</p> <p>15 THE COURT: Then I think -- I think we need to fill 16 it. So let's anticipate filling the day up with necessary 17 testimony.</p> <p>18 MS. JONES: We will -- we will make the necessary -- 19 I mean, to be candid with Your Honor, we'll start -- we'll 20 have to start with a video, but we've got --</p> <p>21 THE COURT: Juries are just --</p> <p>22 MS. JONES: We'll fill it up.</p> <p>23 THE COURT: You know, it is a -- it is a difficult 24 problem. When the Congress originally -- this doesn't need to 25 be on the record.</p>	<p style="text-align: center;">Page 13</p> <p>1 Illinois law, Jo Huskey, will say --</p> <p>2 THE COURT REPORTER: I'm sorry. I didn't hear.</p> <p>3 MR. WALLACE: I'm sorry.</p> <p>4 The plaintiff, Jo Huskey, will say that the bills are 5 paid, and that is <i>prima facie</i> evidence that they're paid. So 6 that's our -- that's our point.</p> <p>7 THE COURT: Yes, ma'am.</p> <p>8 MS. JONES: I have no --</p> <p>9 THE COURT: Dr. Blaivas, I reserve ruling on the 10 reliability of his opinion. I've had some briefing on it. I 11 still don't understand it, so I'm just going to flat ask the 12 question and see if I can get a handle on it before I confront 13 it.</p> <p>14 MS. FITZPATRICK: Okay. I think Your Honor's 15 question was on the pubovaginal sling article that deals with 16 sphincteric deficiency. I'm going to try to explain this.</p> <p>17 Stress urinary incontinence is a symptom of a few 18 different issues. For example, you can have stress urinary 19 incontinence from having a fistula or a hole in your bladder 20 wall. That would cause urine to leak because of that hole. 21 You can have stress urinary incontinence because you have an 22 overactive bladder that is constantly contracting and forcing 23 urine out. You can also have what Ms. Huskey has, what we're 24 dealing with in these particular cases, you can have stress 25 urinary incontinence because the sphincter between your</p>

<p style="text-align: center;">Page 14</p> <p>1 bladder and your urethra is not working properly, either 2 because the urethra has descended or for whatever reason. 3 Those sphincteric deficiencies are the reason that a 4 woman would get either the polypropylene sling or the 5 autologous fascial sling or a Burch procedure. 6 THE COURT: Okay. I understand your answer. 7 What's the objection? If sphincteric incontinence 8 is, in fact, what Ms. Huskey has, your objection relating to 9 this witness's testimony because the article only dealt with 10 sphincteric incontinence has now left me wandering in the 11 wilderness. 12 MS. JONES: I think that the objection is twofold, 13 Your Honor. The paragraph that Your Honor asked for or asked 14 us about out of Dr. Blaivas' report specifically is one that 15 starts out saying that pubovaginal slings using autologous 16 fascia are safer than synthetic slings. 17 And he cites two articles in support of that. One 18 was admittedly a mistake. It's an animal study, and he came 19 back and substituted that. One of those articles that he 20 cites is his own article. First, there's no showing in this 21 case that Mrs. Huskey has been diagnosed with ISD, and, 22 secondly -- 23 THE COURT: Is that what is referred to -- what I 24 just referred to as sphincteric incontinence as opposed to the 25 other kinds of reasons?</p>	<p style="text-align: center;">Page 16</p> <p>1 THE COURT: All right. I'm not putting words in your 2 mouth. Is it your argument that, with your characterization 3 of those two articles, that there is an insufficient basis to 4 establish the reliability of the opinion he offers? Is that 5 what your point is? 6 MS. JONES: It is, Your Honor. 7 THE COURT: All right. Ms. Fitzpatrick. 8 MS. FITZPATRICK: Your Honor, there are a number of 9 articles on Dr. Blaivas' reliance list that go specifically to 10 this issue. What is a key issue in this case is both the 11 comparison of the efficacy, which is one issue, and the safety 12 of these two devices. 13 Dr. Blaivas has for 25-plus years put in autologous 14 fascial slings in hundreds, if not thousands, of patients. He 15 has followed those patients. He is relying on his experience 16 in doing this surgery and what he sees in the surgery, in this 17 way very similar to what Dr. Pramudji testified when she said, 18 "I've put in 300 polypropylene slings and I have very few 19 complications." He's going to testify based on his 20 experience. 21 He's also going to testify, because he's a primary 22 researcher in the area of autologous fascial slings. There 23 are few other people in this country who are more qualified 24 from an experience standpoint, a research standpoint, and a 25 publication standpoint on opining in peer-reviewed articles</p>
<p style="text-align: center;">Page 15</p> <p>1 MS. JONES: Stress urinary incontinence. And, 2 secondly, Your Honor -- I guess twofold. It's Dr. Blaivas 3 cites his own article in support of the statement, and 4 although he says that it remains the gold standard for other 5 surgeries for treating sphincteric incontinence, he never says 6 in here specifically that, one, they're safer than -- or been 7 established to be safer than the midurethral slings, and, B, 8 Your Honor, if you look at the citations or his references, 9 there's not a single reference dated later than 2005, after 10 the midurethral slings became available. 11 They also then cited the Wadie article, Autologous 12 Fascial Sling Vs. Polypropylene Tape, and, again, Your Honor, 13 this article does not support the statement that 14 midurethral -- that autologous fascial slings are safer than 15 the midurethral slings. In fact, what it says is autologous 16 fascial sling and TTV have comparable efficacy in treating 17 SUI, adverse-event-related differences are marginal in the 18 short term, a larger sample size and follow-up are needed to 19 reach a final conclusion, so -- 20 THE COURT: What was the last part of that sentence? 21 After you said the differences are marginal in the short term, 22 the larger sample size what? 23 MS. JONES: I'm not sure I have it exactly. A larger 24 sample size and longer follow-up are needed to draw a final 25 conclusion.</p>	<p style="text-align: center;">Page 17</p> <p>1 about the efficacy of the autologous fascial sling as well as 2 the safety and the complications that you see from those 3 autologous fascial slings. 4 I will, I believe, more than adequately lay a 5 foundation for those particular opinions in his testimony 6 that's based on -- my understanding here was that the issue 7 was the particular article that we had an issue and whether 8 sphincteric deficiency was equivalent to the type of SUI that 9 we are seeing in this case. And the answer to that, and 10 Dr. Blaivas can give you that, is a resounding yes. That's 11 exactly what he's talking about here. 12 So I think that the article is precisely on point, I 13 think his experience, I think his own research, I think the 14 literature is going for him, a more than sufficient foundation 15 for him to opine the -- 16 THE COURT: The literature -- the literature that is 17 on his reliance list beyond the article he wrote? 18 MS. FITZPATRICK: There is literature on his reliance 19 list beyond the article that he wrote. 20 THE COURT: Which is peer-reviewed literature 21 supporting his opinion? 22 MS. FITZPATRICK: That is correct, Your Honor. 23 THE COURT: Okay. Well, I'm inclined to allow it. 24 I'll just have wait until I hear it now. There's still 25 some question in my mind, I'll wait and see what happens.</p>

<p style="text-align: center;">Page 106</p> <p>1 A. No.</p> <p>2 MR. WALLACE: Okay. Give me one second, Your Honor.</p> <p>3 Jo, I think that at this point we don't have any</p> <p>4 further questions for you.</p> <p>5 THE COURT: All right. May the witness step down?</p> <p>6 Thank you very much.</p> <p>7 Call your next witness.</p> <p>8 MS. FITZPATRICK: Your Honor, the plaintiffs call Dr.</p> <p>9 Jerry Blaivas.</p> <p>10 THE COURT: All right.</p> <p>11 MS. FITZPATRICK: Your Honor, this was slightly</p> <p>12 unfortunate timing for Dr. Blaivas who will be with us in just</p> <p>13 one minute.</p> <p>14 THE COURT: Certainly. Talk among yourselves.</p> <p>15 (JERRY BLAIVAS, M.D., HAVING BEEN DULY SWORN, TESTIFIED AS</p> <p>16 FOLLOWS:)</p> <p>17 THE WITNESS: I do.</p> <p>18 THE DEPUTY CLERK: Thank you. Please take the</p> <p>19 witness stand.</p> <p>20 (DIRECT EXAMINATION OF JERRY BLAIVAS BY MS. FITZPATRICK:)</p> <p>21 Q. Good morning, Dr. Blaivas.</p> <p>22 A. Good morning.</p> <p>23 Q. Could you introduce yourself to the jury, please?</p> <p>24 A. Hi. My name is Jerry Blaivas.</p> <p>25 Q. And Dr. Blaivas, where are you from?</p>	<p style="text-align: center;">Page 108</p> <p>1 MS. JONES: No objection, Your Honor.</p> <p>2 THE COURT: It may be introduced, it may be accepted.</p> <p>3 BY MS. FITZPATRICK:</p> <p>4 Q. Dr. Blaivas, this is quite a lengthy document, is that</p> <p>5 right?</p> <p>6 A. I've seen others longer. Yes, it is.</p> <p>7 Q. It's about 43 pages long?</p> <p>8 A. Yes.</p> <p>9 Q. And did you help me prepare some slides that would very</p> <p>10 briefly summarize those pertinent parts of your CV for us</p> <p>11 today?</p> <p>12 A. I did.</p> <p>13 MS. FITZPATRICK: I'd like to display the slides to</p> <p>14 the jury, if there's no objection.</p> <p>15 MS. JONES: I have no objection, Your Honor.</p> <p>16 THE COURT: You may do so.</p> <p>17 BY MS. FITZPATRICK:</p> <p>18 Q. Okay. Dr. Blaivas, if you can take a look at the screen,</p> <p>19 can you briefly summarize for the jury what your educational</p> <p>20 training to become a urologist is?</p> <p>21 A. Sure. I graduated from medical school in 1968 from Tufts</p> <p>22 University. Thereafter I did a general surgical internship</p> <p>23 in, at Boston City Hospital. And then from 1969 to '71 I did</p> <p>24 an additional couple of years as a general surgical resident.</p> <p>25 And then I completed my urology residency in 1976, interrupted</p>
<p style="text-align: center;">Page 107</p> <p>1 A. I'm from New York.</p> <p>2 Q. And what do you do for a living?</p> <p>3 A. I'm a urologist.</p> <p>4 Q. And is that a medical doctor?</p> <p>5 A. It is.</p> <p>6 Q. And can you explain to the jury what, very briefly, what</p> <p>7 the specialty of urology consists of?</p> <p>8 A. It's a surgical subspecialty, and we treat all urological</p> <p>9 diseases which those are diseases that affect the kidneys, the</p> <p>10 bladder, the prostate and the pelvic organs in women. There's</p> <p>11 many other things, but I think that's pertinent to this.</p> <p>12 Q. And, Doctor, before we go too far I'd like to give you a</p> <p>13 document.</p> <p>14 Your Honor, may I approach?</p> <p>15 THE COURT: You may.</p> <p>16 BY MS. FITZPATRICK:</p> <p>17 Q. Dr. Blaivas, can you identify that for me?</p> <p>18 A. Yes, that's my curriculum vitae.</p> <p>19 Q. And it's marked as exhibit 90001, is that correct?</p> <p>20 A. It is.</p> <p>21 Q. And does this accurately reflect both your education,</p> <p>22 training and experience as a urologist?</p> <p>23 A. It does.</p> <p>24 MS. FITZPATRICK: Your Honor, the plaintiffs would</p> <p>25 like to introduce exhibit number 90001 into evidence.</p>	<p style="text-align: center;">Page 109</p> <p>1 by going into the Army from '71 to '73.</p> <p>2 Q. And Dr. Blaivas, are you board certified in any</p> <p>3 specialties?</p> <p>4 A. I am.</p> <p>5 Q. And what specialties?</p> <p>6 A. Urology.</p> <p>7 Q. And how long have you been board certified in urology?</p> <p>8 A. Since 1978.</p> <p>9 Q. And can you briefly tell the jury some of your background</p> <p>10 in the early jobs that you had as a urologist coming out of</p> <p>11 medical school?</p> <p>12 A. Sure. I started off, I was always an academic and also</p> <p>13 practicing clinical doctor and surgeon, so I started off at</p> <p>14 the Tufts University School of Medicine where I rose to the</p> <p>15 rank of associate professor of urology and director of what</p> <p>16 they called the neurourology laboratory. And in those days I</p> <p>17 literally operated four and a half days a week, I was a very,</p> <p>18 very busy surgeon, and I did that for about five years.</p> <p>19 Then I was recruited to come to New York and I went to</p> <p>20 Columbia University College of Physicians and Surgeons where I</p> <p>21 became vice chairman of the department of urology and a</p> <p>22 professor of urology. And in that role I started to</p> <p>23 subspecialize a bit. When I was at Tufts I did virtually all</p> <p>24 different kinds of urology. And by the way, I got at the time</p> <p>25 it was probably one of the largest research grants for</p>

<p style="text-align: center;">Page 110</p> <p>1 evaluating men and women with multiple sclerosis who had 2 bladder problems, incontinence, and difficulties with 3 urination.</p> <p>4 When I got to Columbia I more or less subspecialized in 5 bladder and prostate and pelvic floor problems in men and 6 women, and mostly gave up all the other kinds of surgery that 7 I did.</p> <p>8 Q. How long have you been specializing particularly in 9 pelvic floor issues?</p> <p>10 A. I would say since 1981.</p> <p>11 Q. And is that since you went to Columbia?</p> <p>12 A. Yes.</p> <p>13 Q. Are you still at Columbia, Doctor?</p> <p>14 A. No. In 1992 I resigned and decided to go into full-time 15 private practice and, but also maintain my academic 16 credentials and career, so I joined, it's called the voluntary 17 staff at New York Presbyterian Hospital and I'm now, I'm a 18 clinical professor there, and -- well, that's enough.</p> <p>19 Q. Do you currently treat patients, Doctor?</p> <p>20 A. I do.</p> <p>21 Q. And I think you had said earlier that you did surgeries 22 four and a half days a week early on in your career. Do you 23 still do surgery that often?</p> <p>24 A. No. Now I do it once a week. At least I try to do it 25 once a week.</p>	<p style="text-align: center;">Page 112</p> <p>1 Q. And are you currently affiliated with any hospital?</p> <p>2 A. I am. As I already mentioned, I'm clinical professor at 3 Cornell and I'm a professor also at SUNY Downstate Medical 4 School, and I'm on the voluntary staff at Lenox Hill Hospital.</p> <p>5 Q. Do you teach medical students?</p> <p>6 A. I do.</p> <p>7 Q. And how long have you been teaching medical students?</p> <p>8 A. Since 1976 I guess.</p> <p>9 Q. Can we move on to the last slide?</p> <p>10 Doctor, can you briefly tell the jury about your 11 membership in professional associations and societies?</p> <p>12 A. Sure. Well, they are listed here. I think the important 13 ones for this session is the American Board of Urology, the 14 American Urologic Association, the American Urogynecologic 15 Association, and the International Incontinence Society, and 16 the Society of Pelvic Surgeons, and Society for Urodynamics 17 and Female Urology. All of those societies are involved in 18 some degree to topics we've just been discussing.</p> <p>19 And then the top one, the American Association of 20 Genitourinary Surgeons is more or less of an honorary society 21 that you must be elected into by your peers. And there's only 22 -- there's 9,000 urologists in the country and there's only a 23 hundred members in that, and that's really the highest level 24 of honor you can achieve in our field.</p> <p>25 Q. And when were you elected into that association?</p>
<p style="text-align: center;">Page 111</p> <p>1 Q. And can you tell the jury, very briefly, what your week 2 as a private practice urologist consists of?</p> <p>3 A. Yes. Well, it's rather unique because I still devote a 4 lot of time to academics, so I operate one day a week. I see 5 patients in the office two days a week. And then two more 6 days a week I do clinical and academic research, but I fill in 7 with patients as needed.</p> <p>8 Q. And do you see patients who are referred to you by other 9 doctors?</p> <p>10 A. I do.</p> <p>11 Q. And is there a particular type of complication that you 12 focus your attention on?</p> <p>13 A. Well, yeah. I mean anything that has to do with the 14 pelvic floor in men and women, so I mostly see complications 15 from other kinds of surgeries or other kinds of conditions, or 16 difficult to diagnose and treat people, patients, that have 17 either bladder and prostate problems in men, or incontinence 18 and prolapse problems or recurring infections in women.</p> <p>19 Q. And do you treat women who have complications that arise 20 from pelvic mesh products?</p> <p>21 A. I do.</p> <p>22 Q. And do you see some of those patients as referrals from 23 other physicians?</p> <p>24 A. I see some from referrals from other physicians, but more 25 commonly the patients find me through some other source.</p>	<p style="text-align: center;">Page 113</p> <p>1 A. You didn't write it down for me. I forgot. I think in 2 about 1992 or 3.</p> <p>3 Q. Now, of these professional societies and associations, 4 have you held leadership positions in any of them?</p> <p>5 A. I have.</p> <p>6 Q. And can you tell the jury which ones?</p> <p>7 A. Well, I was president and you work your way up in other 8 positions, but I eventually ended up being president in the 9 Society for Urodynamics and Female Urology, and I've held lots 10 of positions in the American Urologic Association.</p> <p>11 Q. And what --</p> <p>12 A. Excuse me. And also I was on the, lots of positions in 13 the International Incontinence Society.</p> <p>14 Q. And what positions did you hold in the AUA?</p> <p>15 A. Oh, I've been chairman of lots of different committees 16 and I've also, I've been on the American, what's called the 17 guideline panel for the diagnosis and treatment of stress 18 incontinence and the guideline panel for looking at treatment 19 efficacy of incontinence.</p> <p>20 Q. And some of the societies that you brought to our 21 attention, do those deal with the issues of stress urinary 22 incontinence in women?</p> <p>23 A. Well, all of the ones that I mentioned do. In fact, I 24 would say the Society for Urodynamics and Female Urology, the 25 International Incontinence Society, and to a lesser degree I</p>

<p style="text-align: center;">Page 114</p> <p>1 think but it's up there, the American Urogynecologic Society 2 all have dealt with that since their inception. 3 Q. And do you attend meetings of these various associations? 4 A. I do. 5 Q. And have you given presentations at these meetings? 6 A. I have. 7 Q. And have you given presentations that pertain to stress 8 urinary incontinence in women? 9 A. I have. 10 Q. Can we move on to the next one? 11 And Dr. Blaivas, did you serve on any editorial boards 12 of journals, medical journals? 13 A. I do. 14 Q. And can you briefly tell the jury what you do in that 15 regard? 16 A. Well, I just retired a while back as the editor in chief 17 of Neurology and Urodynamics, and that's the official journal 18 for what I consider to be the two most important societies, 19 the International Incontinence Society and the Society for 20 Urodynamics and Female Urology. So I was editor in chief of 21 that, and actually I was the founder of the journal about 25, 22 30 years ago now. And I also, Contemporary Urology is no 23 longer in existence, but I was on the editorial board of that. 24 I was on the editorial board of International Urogynecology 25 Journal and some other ones that we haven't listed here, a</p>	<p style="text-align: center;">Page 116</p> <p>1 I'm going to guess about maybe, maybe a third. 2 Q. And you've also published 240 book chapters, reviews and 3 editorials, too? 4 A. Correct. 5 Q. And do those deal in any way with stress urinary 6 incontinence in women? 7 A. They do. 8 Q. I'm sorry. 9 A. They do. 10 Q. And you've also written, in addition to the book 11 chapters, you've written 12 complete books? 12 A. Well, I've written one and edited the other 11. 13 Q. I was wondering where you found time to write 12 books, 14 so thank you. Do these deal with SUI in women? 15 A. Most of them do, yes. 16 Q. And it also identified here that you've had visiting 17 professorships, named lectureships and research grants. Do 18 any of those deal with SUI in women? 19 A. Yes. The main reason I'm invited as the visiting 20 professor is because of my expertise in either what's called 21 female urology or urogynecology or prostate problems in men. 22 Q. And where have you served as a visiting professor? 23 A. To name a few, University of Pennsylvania, university of 24 Texas, University of Vermont, University of Iowa, Scandinavia, 25 Scandinavian Urological Association, the Spanish, I forget the</p>
<p style="text-align: center;">Page 115</p> <p>1 Brazilian journal, a Korean journal and a Czechoslovakian 2 journal. 3 Q. And the journals that we've identified here that you've 4 worked on, do those deal with issues of stress urinary 5 incontinence in women? 6 A. Yes, I would say it's probably one of the major focuses 7 of two of them. 8 Q. And which two are those? 9 A. The Neurology and Urodynamics and the International 10 Urogynecology Society. 11 Q. And you've also published articles, correct, in 12 peer-reviewed journals? 13 A. I have. 14 Q. It looks like you've got about 193 of those? 15 A. Yes. 16 Q. Does some portion of those articles deal with stress 17 urinary incontinence in women? 18 A. Oh, quite a large number, yes. 19 Q. And do they deal with the treatment of stress urinary 20 incontinence in women? 21 A. Yes. 22 Q. Can you approximate for us about what percentage of the 23 articles that you've published deal with stress urinary 24 incontinence in women? 25 A. This is a rough guess, no one ever asked me that before,</p>	<p style="text-align: center;">Page 117</p> <p>1 name, I can't pronounce the name of the hospital in Spain, and 2 some others. 3 Q. Is it fair to say, Doctor, that in the time since you've 4 graduated from medical school you've spent a good portion of 5 your professional life addressing issues of SUI in women? 6 A. Very much so, yes. 7 MS. FITZPATRICK: Your Honor, is this a good time for 8 a break? I'm moving on to a new topic. 9 THE COURT: It certainly is. 10 Ladies and gentlemen, we'll take a lunch break and 11 today we're going to break until 1:15. I have a short matter 12 to deal with. 13 During the lunch break do not discuss the case among 14 yourselves, permit anyone to discuss it with you or in your 15 presence. Don't read the newspaper. Don't watch TV. Don't 16 listen to the radio. Don't use any computer or social media. 17 Don't do any research. Don't talk about the case or listen 18 about the case. I'll see you back here at 1:15. 19 Court is in recess until 1:15. 20 (A recess was taken at 12:02 p.m.) 21 (The jury entered the courtroom at 1:15 p.m.) 22 THE COURT: Please be seated. 23 Ms. Fitzpatrick. 24 MS. FITZPATRICK: Thank you, Your Honor. 25 BY MS. FITZPATRICK:</p>

<p style="text-align: center;">Page 118</p> <p>1 Q. Before lunch, Dr. Blaivas, we were talking a little bit 2 about your background, education and training. 3 What I want to turn to now is your experience 4 specifically with synthetic mesh, the polypropylene mesh 5 complications.</p> <p>6 How long have you been involved with polypropylene and 7 synthetic mesh complications?</p> <p>8 A. Since the early '80s.</p> <p>9 Q. Okay. Can you describe to the jury what you were doing 10 in the early '80s in this regard?</p> <p>11 A. Yeah. There -- at that time, there was an -- at that 12 time I was treating a lot of people that had lots of failures 13 from other operations and we -- for incontinence, and we were 14 looking for ways to make them better, to help people with 15 incontinence. And I stumbled across this -- the whole concept 16 of using slings. And I -- and I started using what's called 17 an autologous fascial sling, which we'll talk about later, but 18 it's pretty much the same kind of an operation, you know, 19 these things are done, that uses the patient's own tissues.</p> <p>20 And I was invited up to Canada to give some lectures, 21 and there I met a fellow by the name of Ted Morgan who is a 22 gynecologist who had done a lot of synthetic slings, and he 23 was kind of like me. He was a person that saw patients that 24 had these devastating problems, and we were looking for some 25 way to help these poor women.</p>	<p style="text-align: center;">Page 120</p> <p>1 urethra, and so we had to take -- remove the mesh and fix the 2 bladder or the urethra and do pretty extensive reconstructive 3 surgery. And so that's basically what I was doing. We noted 4 how extraordinarily difficult it was to take the mesh out. 5 Q. And at that time were you treating SUI in your practice? 6 A. I was. 7 Q. Okay. And what procedures were you using at that time? 8 A. At that time -- well, we always did what we call natural 9 tissue repairs. At that time I would think probably the 10 commonest operation that we did -- that I did, was something 11 called a Marshall-Marchetti operation, but you can -- they are 12 all fairly similar, but they are all operations that used the 13 patient's own tissue to try to re-support the bladder and the 14 urethra. 15 Q. And before we go any further, Doctor -- and if you don't 16 mind speaking up a little bit, I'm having a little of a hard 17 time hearing you at times. 18 But would you agree with me that SUI, or stress urinary 19 incontinence, is a symptom of an underlying medical condition? 20 A. Yes, it is. 21 Q. And can you explain what some of those underlying medical 22 symptoms -- medical conditions are? 23 A. Sure. The stress incontinence is a symptom. And that 24 means, the symptom is something the patient complains of. And 25 what they complain -- stress incontinence means they complain</p>
<p style="text-align: center;">Page 119</p> <p>1 His experience, though, was with using a synthetic 2 sling called Mersilene, which is a little different than -- 3 excuse me -- called Marlex, which is a little different than 4 the current one, but the point is that he had put a lot of 5 these meshes in and they were devastating, terrible lifestyle 6 kinds of --</p> <p>7 MS. JONES: I'm sorry, Your Honor.</p> <p>8 THE WITNESS: -- altering complications.</p> <p>9 THE COURT: Yes. Sustained.</p> <p>10 MS. JONES: I object as to the relevance of what 11 another doctor has done with another material.</p> <p>12 THE COURT: Let's stick to what you think about what 13 the other doctor told you.</p> <p>14 BY MS. FITZPATRICK:</p> <p>15 Q. Let me ask you, Dr. Blaivas, at that time in the 1980s, 16 did you start performing any surgeries for complications that 17 were arising from the use of synthetic mesh in a woman's 18 pelvis?</p> <p>19 A. I did.</p> <p>20 Q. Okay. And what types of --</p> <p>21 THE COURT: I'm sorry.</p> <p>22 BY MS. FITZPATRICK:</p> <p>23 Q. What types of surgeries were you doing?</p> <p>24 A. Well, we would try -- the problems that we were seeing 25 were fistulas, where they made a hole in the bladder, in the</p>	<p style="text-align: center;">Page 121</p> <p>1 that "I leak urine when I cough or sneeze or lift or bend," 2 anything that puts pressure on the abdomen. 3 So the commonest cause of this -- of stress 4 incontinence, the commonest underlying condition, is a weak 5 sphincter. 6 Now, if you look at my hand and my finger here, if 7 that's -- my fist is the bladder and my thumb is the urethra, 8 the bladder is supposed to store urine, so it fills up, gets 9 bigger and bigger, and then when you want to urinate, you let 10 it go through the urethra. 11 What stops you from leaking all the time is a muscle 12 that's -- that's wrapped around the sphincter -- or wrapped 13 around the urethra called the sphincter. A normal sphincter 14 can withstand whatever stress there is. If I punch you in the 15 stomach, it closes. If you cough, it closes. 16 In a patient with what we call sphincteric 17 incontinence or a weak sphincter, a patient with a weak 18 sphincter, when they cough, the muscle isn't strong enough and 19 the urine gets forced by the muscle and you leak. That's the 20 commonest cause. 21 Q. Is that the type of stress urinary incontinence that 22 Mrs. Huskey has? 23 A. Yes. 24 Q. Okay. And is that condition -- can that condition be 25 treated with a polypropylene midurethral sling like the TVT-O?</p>

<p style="text-align: center;">Page 122</p> <p>1 A. It can.</p> <p>2 Q. And can it also be treated with this autologous fascial</p> <p>3 sling that you mentioned earlier?</p> <p>4 A. Yes, it can.</p> <p>5 Q. And is that autologous fascial sling, is that also</p> <p>6 sometimes called a pubovaginal sling?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. With that by way of background, have you ever used</p> <p>9 synthetic slings, polypropylene slings, to treat women who</p> <p>10 have stress urinary incontinence?</p> <p>11 A. Yes, I have.</p> <p>12 Q. And when did you do that?</p> <p>13 A. Sometime either -- I'm not exactly sure when. It would</p> <p>14 have either been the late '90s or early or mid-part of</p> <p>15 the 20 -- maybe 2003, 2004, 2005. I don't have an independent</p> <p>16 recollection of exactly.</p> <p>17 Q. And have you stopped using synthetic slings in your</p> <p>18 patients?</p> <p>19 A. I'm sorry, I didn't hear the question.</p> <p>20 Q. Have you stopped using synthetic slings in your patients?</p> <p>21 A. For practical purposes, yes.</p> <p>22 Q. And why -- first of all, I will ask you what you mean by</p> <p>23 for practical purposes?</p> <p>24 A. Well, I think whenever we -- whenever we make decisions,</p> <p>25 of course, the patient will make the decision. And I present</p>	<p style="text-align: center;">Page 124</p> <p>1 MS. JONES: Objection, Your Honor. I believe we're</p> <p>2 getting into cumulative and repetitive testimony.</p> <p>3 THE COURT: Overruled.</p> <p>4 THE WITNESS: I'm sorry. The question?</p> <p>5 BY MS. FITZPATRICK:</p> <p>6 Q. I was asking you, you mentioned just a couple minutes ago</p> <p>7 or a minute or two ago that you would never implant a TTVT-O</p> <p>8 device into a patient, and I'm asking you why you would never</p> <p>9 implant a TTVT-O device into any patient.</p> <p>10 A. Because I think the -- the risk of refractory</p> <p>11 life-altering kinds of pain, particularly pain, is too great,</p> <p>12 and it simply doesn't occur -- or almost never occurs with --</p> <p>13 I'm sorry. I forgot again. You asked me if -- I'm sorry to</p> <p>14 ask you to repeat the question again.</p> <p>15 Q. I had asked you if you would -- why you would never</p> <p>16 implant a TTVT-O into any of your patients?</p> <p>17 A. Versus another synthetic?</p> <p>18 Q. Versus another synthetic sling. Thank you for</p> <p>19 clarifying.</p> <p>20 A. Yeah. Because in my hands, I think the chances of</p> <p>21 getting a serious complication with -- with what's called a</p> <p>22 retropubic sling are so much lower than with the TTVT-O, that I</p> <p>23 don't think -- there's no reason to subject them to the extra</p> <p>24 risk.</p> <p>25 Q. Okay. And when you refer to a retropubic sling, can you</p>
<p style="text-align: center;">Page 123</p> <p>1 the pros and cons. But we always weigh the risks against the</p> <p>2 benefits. And sometimes, even if there is high risks, they</p> <p>3 may outweigh -- they may outweigh the fact that the benefits</p> <p>4 are -- may be the only thing left to do.</p> <p>5 So, for example, in a very, very obese -- or an obese,</p> <p>6 very older woman, where it would be desirable to do a fast</p> <p>7 operation, it might be that we would accept the risks of</p> <p>8 something like a -- well, I wouldn't use the TTVT-O, but other</p> <p>9 synthetic slings, accept the -- be willing to accept the risk</p> <p>10 because there is no other good treatment and the other</p> <p>11 operations are even more risky for that particular patient.</p> <p>12 Q. How often would you recommend a synthetic sling to a</p> <p>13 patient over a natural tissue repair?</p> <p>14 A. Well, again, I present the pros and cons. If they ask me</p> <p>15 what I would do, I would never recommend a synthetic sling</p> <p>16 over an autologous sling, except in a kind of circumstance</p> <p>17 that I just described.</p> <p>18 Q. Okay. And you said just a moment ago that you would</p> <p>19 never implant the TTVT-O. Why would you not implant a TTVT-O</p> <p>20 device?</p> <p>21 A. Well, because I think it has inherent risks that the</p> <p>22 other kinds don't have, at least in -- you know, the other</p> <p>23 kinds don't have. I don't think there is any --</p> <p>24 MS. JONES: (Standing.)</p> <p>25 THE COURT: Excuse me. Yes, ma'am?</p>	<p style="text-align: center;">Page 125</p> <p>1 tell the jury what retropubic sling that Ethicon makes?</p> <p>2 A. It's called the TTVT.</p> <p>3 Q. And is that the predecessor to the TTVT-O?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And what surgery do you generally perform in women</p> <p>6 who need surgical intervention for SUI today?</p> <p>7 A. I still perform the autologous fascial sling.</p> <p>8 Q. And about how many of those pubovaginal slings or</p> <p>9 autologous fascial slings have you implanted over the course</p> <p>10 of your career?</p> <p>11 A. I would say 1500 to 2,000 maybe.</p> <p>12 Q. And do you also perform surgeries to remove polypropylene</p> <p>13 midurethral slings from women who have complications?</p> <p>14 A. I do.</p> <p>15 Q. Okay. And about how many polypropylene slings have you</p> <p>16 removed from women?</p> <p>17 A. Probably 60 to 75, when I include going back to the '90s</p> <p>18 and '80s.</p> <p>19 Q. Okay. And have you removed obturator slings from women?</p> <p>20 A. I have.</p> <p>21 Q. And let me ask you, on average, how long is the surgery</p> <p>22 to explant a polypropylene sling from a woman?</p> <p>23 A. It's very, very varied, although I would say it can be as</p> <p>24 short as 45 minutes and as long as -- I've spent six hours.</p> <p>25 Q. And does that depend on the degree of complications that</p>

<p style="text-align: center;">Page 126</p> <p>1 women have?</p> <p>2 A. Well, it depends on how extensive the scarring is, where</p> <p>3 it is, whether it's -- whether we need to try to remove the</p> <p>4 entire thing or not -- the entire sling or not.</p> <p>5 Q. In your experience, Doctor, in both implanting</p> <p>6 polypropylene slings and during the explant surgeries for</p> <p>7 polypropylene slings, are the surgeries to take the slings out</p> <p>8 more complicated than the surgeries required to put them in?</p> <p>9 A. Oh, it's an order of magnitude more difficult. It's not</p> <p>10 even in the same league.</p> <p>11 MS. FITZPATRICK: Your Honor, at this time I would</p> <p>12 like to tender Dr. Blaivas to give opinions in this case in</p> <p>13 the art of gynecological matters.</p> <p>14 THE COURT: Any voir dire?</p> <p>15 MS. JONES: I have no voir dire at this time, Your</p> <p>16 Honor.</p> <p>17 THE COURT: All right. He may offer opinions in that</p> <p>18 field.</p> <p>19 MS. FITZPATRICK: Thank you.</p> <p>20 BY MS. FITZPATRICK:</p> <p>21 Q. Now, Doctor, I want to turn to Mrs. Huskey. You have met</p> <p>22 her before, haven't you?</p> <p>23 A. I have.</p> <p>24 Q. Can you tell the jury when you met Mrs. Huskey before?</p> <p>25 A. I did an independent medical examination on her. I don't</p>	<p style="text-align: center;">Page 128</p> <p>1 Q. And what was your impression of Mrs. Huskey at that</p> <p>2 meeting?</p> <p>3 A. Oh, I found her to be a very likeable, optimistic, upbeat</p> <p>4 kind of a woman who was trying desperately to -- to get rid of</p> <p>5 this problem that's plaguing her.</p> <p>6 Q. And during that --</p> <p>7 A. And likeable. I don't know if I said that.</p> <p>8 Q. You did.</p> <p>9 Can you describe for the jury how you went about taking</p> <p>10 a history from Mrs. Huskey at that exam?</p> <p>11 A. What -- the first thing she -- that she did was she</p> <p>12 completed, I think, completed a questionnaire about what her</p> <p>13 symptoms were. And then I would have reviewed that and sat</p> <p>14 down with her and asked her very detailed questions about --</p> <p>15 about what her symptoms were, about what her prior history</p> <p>16 was, what her treatment has been, and then I examined her.</p> <p>17 Q. Okay. And the history and physical that you did with</p> <p>18 Mrs. Huskey on that day, is that the same as you do for any</p> <p>19 other patient who presents in your office as a new patient?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And you didn't do anything differently in this</p> <p>22 case because she came to you seeking an expert opinion in her</p> <p>23 lawsuit, did you?</p> <p>24 A. I did not.</p> <p>25 Q. Now, you know that Mrs. Huskey had a TVT-O implanted in</p>
<p style="text-align: center;">Page 127</p> <p>1 remember exactly when, some months back.</p> <p>2 Q. Okay. And did you do that at the request of her lawyers</p> <p>3 in this case?</p> <p>4 A. I did.</p> <p>5 Q. And what were you asked to do in that exam?</p> <p>6 A. I was asked to review her records, to examine her, and to</p> <p>7 render an opinion about what's causing her current symptoms.</p> <p>8 Q. Okay. And did you have an opportunity to review her</p> <p>9 medical records?</p> <p>10 A. I did.</p> <p>11 Q. And did you have an opportunity to review the testimony</p> <p>12 of her treating physicians in this case?</p> <p>13 A. I did.</p> <p>14 Q. And did you have an opportunity to actually perform an</p> <p>15 internal examination on Mrs. Huskey?</p> <p>16 A. I did.</p> <p>17 Q. And did you have a chance to sit down with her one on one</p> <p>18 and talk to her about her medical history?</p> <p>19 A. Yes.</p> <p>20 Q. And did you do each of these things before you rendered</p> <p>21 an opinion on the cause of her current pain?</p> <p>22 A. Of course.</p> <p>23 Q. Okay. Let me ask you, where did you meet with</p> <p>24 Mrs. Huskey?</p> <p>25 A. In my office in New York.</p>	<p style="text-align: center;">Page 129</p> <p>1 February of 2011; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. And do you recall who implanted that device?</p> <p>4 A. Dr. Byrkit.</p> <p>5 Q. And did you have a chance to review Dr. Byrkit's records?</p> <p>6 A. I did.</p> <p>7 Q. And did you have a chance to review Dr. Byrkit's trial</p> <p>8 testimony in this case as well?</p> <p>9 A. I did.</p> <p>10 Q. And did you look at those and take those into</p> <p>11 consideration when you were forming your own opinions in this</p> <p>12 case?</p> <p>13 A. Yes, I did.</p> <p>14 Q. Okay. So can you tell the jury very briefly what you</p> <p>15 learned about Mrs. Huskey's implant surgery and her immediate</p> <p>16 follow-up care for the first one to two months after she had</p> <p>17 the sling implanted?</p> <p>18 A. Well, the implant surgery was done -- was uncomplicated</p> <p>19 except for what Dr. Byrkit described as a buttonhole, which is</p> <p>20 really going to be hard to describe in words, but, basically,</p> <p>21 the tape went from -- it's supposed to stay inside the vaginal</p> <p>22 wall, if you think of the vagina like your lip, so it's</p> <p>23 supposed to be all inside your lip. And it would be as if you</p> <p>24 put it inside -- went from the outside to the inside and then</p> <p>25 back outside again. So, basically, it went in and out, and</p>

<p style="text-align: center;">Page 130</p> <p>1 it's supposed to just stay on the inside. She recognized 2 that, so -- and withdrew the sling and then reinserted it 3 and -- into the proper place, and then sutured over the holes 4 that were made in the vaginal wall.</p> <p>5 Q. And did there come a time after that implant surgery in 6 February that Mrs. Huskey had some complications related to 7 the TVT-O device?</p> <p>8 A. She did.</p> <p>9 Q. Okay. Can you tell the jury what those were?</p> <p>10 A. Yes. Dr. Byrkit noted that the sling material had eroded 11 or worn its way out into the -- inside of the vagina, so, 12 remember, it's supposed to be inside of your -- it's supposed 13 to be inside the vaginal wall, but part of it on the left side 14 was outside of the vaginal wall.</p> <p>15 Q. And so did that require further treatment from 16 Dr. Byrkit?</p> <p>17 A. It did.</p> <p>18 Q. And what was that treatment?</p> <p>19 A. Well, first she tried to treat it with some local vaginal 20 creams, an estrogen cream that you put over it, hoping that it 21 would heal over, but it did not. And then eventually, about 22 five or six months later, she did an operation to try to -- 23 try to cover it with the tissue again, but ultimately that 24 failed as well.</p> <p>25 Q. So the procedure -- let me make sure I've got the dates</p>	<p style="text-align: center;">Page 132</p> <p>1 A. That was, I think, in November of 2011.</p> <p>2 Q. And who performed that surgery?</p> <p>3 A. Dr. Siddique.</p> <p>4 Q. Do you have an understanding of why Dr. Siddique 5 performed the removal surgery instead of Dr. Byrkit?</p> <p>6 A. Well, according to Dr. Byrkit's testimony, she wasn't 7 that familiar with how to do it and she thought it would be 8 better done by someone that had more expertise in -- in fixing 9 these things.</p> <p>10 Q. And, based on your experience in treating mesh 11 complications and in removing mesh surgery, were you surprised 12 that Dr. Byrkit referred Mrs. Huskey to Dr. Siddique for the 13 removal surgery?</p> <p>14 MS. JONES: Objection.</p> <p>15 THE COURT: Sustained.</p> <p>16 BY MS. FITZPATRICK:</p> <p>17 Q. Based on your experience with removal surgeries, Doctor, 18 did you find it unusual that a primary-care physician or 19 gynecologist would refer out a patient to a specialist for a 20 removal surgery?</p> <p>21 MS. JONES: Objection.</p> <p>22 THE COURT: Tell me why that would be relevant.</p> <p>23 MS. FITZPATRICK: Your Honor, it goes to the issues 24 of how complicated these removal surgeries are and they're not 25 generally something that are done by the first line of</p>
<p style="text-align: center;">Page 131</p> <p>1 right. The procedure where Dr. Byrkit tried to surgically 2 repair the mesh was in June of 2011; is that right?</p> <p>3 A. Correct.</p> <p>4 Q. Okay. And why did she have that excision surgery 5 performed?</p> <p>6 A. Well, that wasn't the excision surgery. That was the 7 surgery to close over the -- to close it, close it over. So 8 it was an exposed piece. Imagine if you scraped your elbow, 9 okay? And then what she did is she, to cover the scrape, 10 which in this case is the sling, she made an incision around 11 the scrape and then tried to pull the skin over it to cover it 12 and then sutured that up.</p> <p>13 Q. Okay. How did that work?</p> <p>14 A. It did not work.</p> <p>15 Q. Okay. And did Mrs. Huskey have subsequent complications 16 related to the sling?</p> <p>17 A. Well, she -- Dr. Byrkit actually before that had advised 18 her to have -- to try to have sex because she hadn't had sex 19 yet, and to see if that was causing any symptom, and, in fact, 20 it did, so sex was painful. And then the exposure of the mesh 21 sling was getting bigger over time, not smaller.</p> <p>22 Q. And did that lead to Mrs. Huskey having a removal 23 surgery?</p> <p>24 A. It did.</p> <p>25 Q. Do you remember when that was?</p>	<p style="text-align: center;">Page 133</p> <p>1 physician who put in these surgeries, and when they get more 2 complicated, you have to ramp it up to an extra level of 3 specialty.</p> <p>4 THE COURT: And that's what Dr. Byrkit said, right?</p> <p>5 MS. FITZPATRICK: Well, Dr. Byrkit said that she 6 referred -- she referred it to Dr. Siddique.</p> <p>7 THE COURT: Your testimony is good enough. Let's 8 move on.</p> <p>9 MS. FITZPATRICK: Okay. Fine, Your Honor. Thank 10 you.</p> <p>11 BY MS. FITZPATRICK:</p> <p>12 Q. Now, before we go any further, I want to ask you, you had 13 testified a little bit earlier that you first became familiar 14 with complications of synthetic mesh slings in the 1980s. Is 15 that right?</p> <p>16 A. Correct.</p> <p>17 Q. And at that time did you become familiar with the types 18 of complications that a physician could see with the use of a 19 synthetic sling?</p> <p>20 A. I did.</p> <p>21 Q. And what types of complications back in the '80s -- and I 22 want to clarify, these were not the TVT or the TVT-O device, 23 but back in the '80s, what type of complications were you 24 seeing with those synthetic slings?</p> <p>25 A. Well, I would say the commonest is that the sling caused</p>

<p style="text-align: center;">Page 134</p> <p>1 a blockage, that it was just too tight.</p> <p>2 And the second commonest, and this is by recollection,</p> <p>3 this -- the second commonest was -- or maybe just as common</p> <p>4 was pain. And then what we now call overactive bladder</p> <p>5 symptoms, but wasn't even -- that word didn't exist then, but</p> <p>6 frequency of urination having to run to the bathroom and not</p> <p>7 getting there in time, and then fistulas, a fistula is a hole</p> <p>8 in either the bladder or the urethra through which the urine</p> <p>9 leaks out.</p> <p>10 Q. And at that time in 1980s and early 1990s that you first</p> <p>11 started seeing synthetic-sling-related complications, was</p> <p>12 there any information available in the medical literature to</p> <p>13 inform surgeons like yourself on how to treat those</p> <p>14 complications?</p> <p>15 A. Not really.</p> <p>16 MS. JONES: Objection, Your Honor.</p> <p>17 THE COURT: Overruled.</p> <p>18 BY MS. FITZPATRICK:</p> <p>19 Q. And then fast forwarding to the late 1990s and 2000s, I</p> <p>20 think you said you had used some retropubic polypropylene</p> <p>21 slings at that time. Is that right?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And at that time when you were performing those</p> <p>24 surgeries -- let me ask you this, Doctor, I don't think I</p> <p>25 asked you. Why did you stop doing those surgeries?</p>	<p style="text-align: center;">Page 136</p> <p>1 THE COURT: I'm going to allow it.</p> <p>2 THE WITNESS: No, I did not.</p> <p>3 BY MS. FITZPATRICK:</p> <p>4 Q. How did you figure out, for lack of a better word, how to</p> <p>5 deal with the mesh-related complications that you were</p> <p>6 starting to see in your practice?</p> <p>7 A. I'm sorry to say, mostly just trial and error and</p> <p>8 conferring with colleagues. I mean, there are a number of</p> <p>9 people like me around the country that -- that were starting</p> <p>10 to see these complications in -- with increased frequency, and</p> <p>11 we interacted and conversed a lot about it, during the course</p> <p>12 of informational meetings about it and interact.</p> <p>13 Q. Are you still working on trying to establish or figure</p> <p>14 out how to deal with mesh-related complications for women?</p> <p>15 A. Yes, I am.</p> <p>16 Q. And is that an ongoing process that you're engaged in</p> <p>17 with colleagues from around the country?</p> <p>18 A. Only in an informal way, but yes.</p> <p>19 Q. Do you think you are at a point, Doctor, having worked on</p> <p>20 this issue for so long, that you understand how to treat each</p> <p>21 and every complication related to mesh that's presented to</p> <p>22 you?</p> <p>23 A. I wish I did. No, I don't.</p> <p>24 Q. And what do you do when a patient comes to you with a</p> <p>25 mesh-related complication that you don't know how to deal</p>
<p style="text-align: center;">Page 135</p> <p>1 A. The slings? The synthetics?</p> <p>2 Q. Yes, the synthetic slings.</p> <p>3 A. Because I was very, very experienced at that time, and so</p> <p>4 I thought it would be just duck soup to just switch from one</p> <p>5 sling to another. But the very first one that I put in was</p> <p>6 too tight. And after just a month or two, I had to cut it.</p> <p>7 Then the next one I put in was too loose, and she was still</p> <p>8 incontinent. And then I did a few -- don't ask why, but I did</p> <p>9 a few more, and I started to get it just right, but I said,</p> <p>10 this isn't -- I don't see any reason to do it. I mean, it</p> <p>11 was -- so I stopped.</p> <p>12 Q. Okay. And was that about the time that you started to</p> <p>13 see women with mesh-related complications?</p> <p>14 A. Are you talking about early the '90s?</p> <p>15 Q. Mid-2000s.</p> <p>16 A. Oh, the mid-2000s, absolutely, yeah, there were.</p> <p>17 Q. And at that time when you were starting to see and treat</p> <p>18 women with mesh-related complications, was there any</p> <p>19 literature available that told you how to address and treat</p> <p>20 those mesh-related complications?</p> <p>21 A. Not that I'm aware of.</p> <p>22 Q. Did you have any information from Ethicon on how to deal</p> <p>23 with mesh-related complications at the time you started to see</p> <p>24 them?</p> <p>25 MS. JONES: Objection, Your Honor.</p>	<p style="text-align: center;">Page 137</p> <p>1 with?</p> <p>2 A. You do the best you can. To start, you do no harm, okay?</p> <p>3 And the doing-no-harm part means that you -- at least in my</p> <p>4 opinion, I have to sacrifice removing all of the mesh</p> <p>5 sometimes because the complications -- because the potential</p> <p>6 complications of removing the mesh in my judgment are too</p> <p>7 great, so we do a lesser operation than I might otherwise</p> <p>8 think would be necessary.</p> <p>9 Q. Okay. And, Dr. Blaivas, where do your patients come</p> <p>10 from? Are they all from the New York area?</p> <p>11 A. No, they come from all over really. I mean, even from</p> <p>12 Europe.</p> <p>13 Q. Doctor, I'd like to turn back to your review of</p> <p>14 Mrs. Huskey's medical records. And did you review the records</p> <p>15 of Dr. Siddique's removal surgery?</p> <p>16 A. I did.</p> <p>17 MS. FITZPATRICK: Your Honor, may I approach?</p> <p>18 THE COURT: You may.</p> <p>19 BY MS. FITZPATRICK:</p> <p>20 Q. And, Doctor, I've just given you a copy of Plaintiffs'</p> <p>21 Exhibit 91102, that's already admitted into evidence. Is that</p> <p>22 a copy of the operating note from Dr. Siddique relating to</p> <p>23 Mrs. Huskey's removal surgery?</p> <p>24 A. Yes, it is.</p> <p>25 Q. And is this one of the documents that you reviewed in</p>

<p style="text-align: center;">Page 138</p> <p>1 connection with your testimony and your opinions in this case?</p> <p>2 A. Yes, it is.</p> <p>3 Q. And, Doctor, before we go into this in detail, I'd like</p> <p>4 to show you something and ask you to identify for me what this</p> <p>5 is.</p> <p>6 A. That's called a Metzenbaum scissors.</p> <p>7 Q. And are Metzenbaum scissors used for the implant of the</p> <p>8 TVT-O device into women?</p> <p>9 A. By most people, I think, yes.</p> <p>10 MS. FITZPATRICK: Okay. Your Honor, may I approach?</p> <p>11 THE COURT: You may.</p> <p>12 BY MS. FITZPATRICK:</p> <p>13 Q. And, Doctor, are those the scissors that were used by</p> <p>14 Dr. Byrkit to implant Mrs. Huskey's TVT-O? That type of</p> <p>15 scissor, I should say.</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And in reviewing the operating note from</p> <p>18 Dr. Siddique's removal surgery, what type of scissors did he</p> <p>19 use for the removal surgery?</p> <p>20 A. Something called curved Mayo.</p> <p>21 Q. Is that this type of scissor?</p> <p>22 A. It is.</p> <p>23 MS. FITZPATRICK: Your Honor, may I approach?</p> <p>24 THE COURT: You may.</p> <p>25 BY MS. FITZPATRICK:</p>	<p style="text-align: center;">Page 140</p> <p>1 not do any damage, when you -- when you cut -- in</p> <p>2 Dr. Siddique's description of taking the sling out, part of</p> <p>3 what he had to do is it was thickened and scarring and he had</p> <p>4 to put a suture --</p> <p>5 THE COURT: Hold on just a second.</p> <p>6 MS. JONES: Your Honor?</p> <p>7 THE COURT: Can we see you at sidebar?</p> <p>8 (The following occurred at sidebar.)</p> <p>9 THE COURT: If I recall correctly, and I just want to</p> <p>10 be sure because I realize the sensitivity of this, Ethicon did</p> <p>11 not challenge this area when they made their motions, the</p> <p>12 Daubert motions, and the motions in limine. Is that correct?</p> <p>13 MS. JONES: Challenge specifically his -- well, in</p> <p>14 terms of a Daubert motion, we challenged Dr. Blaivas in his</p> <p>15 entirety, including several other things. I don't think that</p> <p>16 there was anything nearly quite so specific as his discussions</p> <p>17 of the surgery. However, to the extent that he intends to go</p> <p>18 any further about how the TVT is inserted, we will, because of</p> <p>19 the fact he's clearly never implanted one.</p> <p>20 THE COURT: What I was -- the one thing I did exclude</p> <p>21 that I recall was -- and I don't know where he's going -- but</p> <p>22 I excluded his discussion of the competence of other</p> <p>23 physicians.</p> <p>24 MS. FITZPATRICK: Oh, let me -- maybe I can tell you</p> <p>25 where we're going, Judge, and that will make it easier.</p>
<p style="text-align: center;">Page 139</p> <p>1 Q. And, Doctor, can you hold those scissors up for the jury,</p> <p>2 please? And explain to them the significance, if any, in the</p> <p>3 different in size of those scissors used for the implant</p> <p>4 surgery versus the ones used for the explant surgery.</p> <p>5 A. Sure. Well, the Metzenbaum scissors, the ones that are</p> <p>6 used to implant the surgery, are very delicate dissecting</p> <p>7 scissors. They don't cut with the point. I could go like</p> <p>8 this and they're not sharp. What you do is you can push, and</p> <p>9 then the way you use it, you see the way I'm holding it in my</p> <p>10 hand, it's a real fingertip kind of thing. So you can feel</p> <p>11 what you're doing, and then the way you implant it is you push</p> <p>12 and then you gently open and close, and this is all the</p> <p>13 movement that you do -- that you do. Just like that. Okay?</p> <p>14 You can't -- it's very difficult to do any damage with these</p> <p>15 kind of scissors.</p> <p>16 And then when you've finished this dissection, all</p> <p>17 you've done is you've made a channel in the tissue that's that</p> <p>18 size. And then that channel is used to introduce the sling</p> <p>19 later on.</p> <p>20 Q. And then can you turn to the other pair of scissors? I'm</p> <p>21 sorry, what did you call those again?</p> <p>22 A. This is called a curved Mayo. These are much heavier</p> <p>23 scissors, okay? And they're not delicate, gentle scissors.</p> <p>24 They're used to cut heavy, hard things out. And whereas in</p> <p>25 the first instance, we are using a very gentle technique to</p>	<p style="text-align: center;">Page 141</p> <p>1 THE COURT: All right.</p> <p>2 MS. FITZPATRICK: He is drawing a distinction between</p> <p>3 the very fine scissors that are used for the implant and the</p> <p>4 heavier scissors that are used for the explant, and the</p> <p>5 significance of that is the damage to the pelvic tissue and</p> <p>6 the subsequent scar tissue that develops when you are -- when</p> <p>7 you have to use basically a heavier scissor to extract.</p> <p>8 So he's going to talk about Dr. Siddique's record,</p> <p>9 what Dr. Siddique used, as part of the basis for his opinions</p> <p>10 that the scar tissue that she has around her vagina is caused</p> <p>11 by the TVT-O and the accompanying procedure, the device and</p> <p>12 the procedures is basically it.</p> <p>13 MS. JONES: I don't think -- that opinion certainly</p> <p>14 has not been disclosed in that way.</p> <p>15 MS. FITZPATRICK: The cause of -- it certainly is.</p> <p>16 He's here on specific causation as to what is the cause of her</p> <p>17 current injuries, and the cause of her current injuries is</p> <p>18 the -- the device and the procedure that was used with the</p> <p>19 TVT-O. He's very clearly stated that.</p> <p>20 MS. JONES: It doesn't -- well, certainly doesn't say</p> <p>21 anything about the removal procedure being specifically the</p> <p>22 cause of it.</p> <p>23 MS. FITZPATRICK: He testified about this in his</p> <p>24 deposition, specifically about the explant surgery.</p> <p>25 THE COURT: I'm going to allow it. Let's go.</p>

<p style="text-align: center;">Page 142</p> <p>1 MS. FITZPATRICK: Thank you. 2 (Sidebar concluded.) 3 BY MS. FITZPATRICK: 4 Q. I think I have to wake you back up, Dr. Blaivas. We are 5 all done with that. 6 Can you describe to the jury your understanding of the 7 removal surgery that Mrs. Huskey had to undergo to remove the 8 TVT-O sling by Dr. Siddique? 9 A. Yes. He identified that by the time he actually 10 performed the surgery, the mesh had eaten through the entire 11 right side of the vagina. So it was extending from just 12 underneath the urethra, which is, remember, like my thumb, all 13 the way to the end -- to the side of the vagina, kind of like 14 a bow string. And he described that as being very easy. He 15 just cut it. 16 But when he cut it, he noted that the tissue that was 17 going into the vaginal wall was very thickened and -- and 18 looked infected. 19 On the left side, though, it was much more difficult to 20 remove, and that's why he had to use those unmentionable 21 scissors. 22 Q. Oh, you can mention them. 23 A. Okay. So he had to use those scissors, and in doing so, 24 you have to take much more vaginal -- much more of the vaginal 25 wall tissue to be sure to get all of the sling out. And so he</p>	<p style="text-align: center;">Page 144</p> <p>1 A. Because it's simply -- it's just too difficult and too 2 morbid, which means that if you tried to remove it all, the 3 complications to the patient from removing it may be even 4 worse than not removing it. 5 Q. Is this a particular risk with the TVT-O device? 6 MS. JONES: Judge, objection. 7 THE COURT: Hang on just one second. 8 Sustained as to leading. 9 BY MS. FITZPATRICK: 10 Q. Is this a particular risk with any -- with any specific 11 kind of midurethral polypropylene -- polypropylene midurethral 12 sling? 13 A. Yes, I think it's unique to transobturator slings, of 14 which the TVT-O is one. 15 Q. And why is it particular to transobturator slings? 16 A. Because the sling is placed basically into the upper part 17 of the thigh, which is not a place that gynecologists and 18 urologists usually operate. So to start with, it's a -- it's 19 a foreign place for us. And, in fact, few people actually 20 operate there for any reason. 21 MS. JONES: Your Honor, I'm going to object. 22 THE COURT: Sustained. The jury will disregard. 23 BY MS. FITZPATRICK: 24 Q. Do you perform surgeries similar to the surgery that 25 Dr. Siddique performed on Mrs. Huskey?</p>
<p style="text-align: center;">Page 143</p> <p>1 did that and then he had to -- because it was so difficult, he 2 had to put a stitch in it and pull back hard on the stitch 3 before he -- before he could remove all of the -- in order to 4 remove it all. 5 And then he was left with a defect, a hole or a space 6 where the sling was, so he had to -- the word I'm going to 7 use, he had to create flaps, and what that means is that he 8 had to dissect underneath the wall of the vagina because, you 9 remember, there's -- there's a long strip that's missing of 10 the vaginal wall. And if you just pulled it together, it 11 would likely just spring apart again. 12 So the way we -- the way we fix that is by creating 13 what's called a flap, to make the tissue nice and loose, and 14 that's what he did, so he created a flap, and then he 15 irrigated the wound, he squirted an antibiotic solution on 16 it -- solution on it, in an attempt to treat what he thought 17 was the infection, and to prevent it from becoming infected 18 again. And then he closed the vaginal wall. 19 Q. And, Dr. Blaivas, when you were explaining that to the 20 jury, you used the term "remove it all." 21 A. Yeah. 22 Q. Is it your understanding that Dr. Siddique was able to 23 remove the entire TVT-O from Mrs. Huskey's pelvis? 24 A. No, he did not remove it all. 25 Q. And why could he not remove it all?</p>	<p style="text-align: center;">Page 145</p> <p>1 A. I do. 2 Q. And how long did Mrs. Huskey's explant surgery take? 3 A. You know, I'd have to look. 4 Q. Okay. 5 A. Just under two hours. 6 Q. And is that -- in your experience, education and 7 training, particularly in your performing surgeries similar to 8 that surgery, did it require an extensive dissection of 9 Mrs. Huskey's pelvis? 10 MS. JONES: Objection, Your Honor. 11 THE COURT: Overruled. 12 THE WITNESS: They're all extensive dissections to 13 get that out, to get them out. But this wasn't more extensive 14 than the typical extensive dissection for this. 15 BY MS. FITZPATRICK: 16 Q. Okay. Was it less extensive? 17 A. No. 18 Q. And in the surgeries -- 19 A. Excuse me, yes, because the right side was already -- the 20 right side had already completely eroded. That's not a good 21 thing but it's -- but it made it easier. 22 Q. So the surgery -- am I correct in saying the surgery on 23 the left side, the dissection was more extensive than on the 24 right side? 25 A. Yes.</p>

<p style="text-align: center;">Page 146</p> <p>1 Q. Okay. And in performing surgeries similar to the surgery 2 that Mrs. Huskey has, what are your observations of how the 3 mesh appears when you remove it?</p> <p>4 MS. JONES: Objection, Your Honor.</p> <p>5 THE COURT: Hang on just one second.</p> <p>6 I think you had a ruling on this. Do you want to 7 take a look?</p> <p>8 MS. FITZPATRICK: Pardon me, Your Honor?</p> <p>9 THE COURT: I think I ruled on testimony that he 10 might offer regarding strength degradation, et cetera, didn't 11 I?</p> <p>12 MS. FITZPATRICK: I -- hang on for a minute.</p> <p>13 THE COURT: I'll take my chances on my memory. I'll 14 sustain the objection.</p> <p>15 MS. FITZPATRICK: Okay. I didn't think I was asking 16 about that topic, Your Honor. I think that's why I'm looking 17 a little puzzled.</p> <p>18 THE COURT: Why don't you ask it again then and I'll 19 listen more closely.</p> <p>20 MS. FITZPATRICK: Okay.</p> <p>21 BY MS. FITZPATRICK:</p> <p>22 Q. Dr. Blaivas, when you perform explant surgeries, what 23 does the mesh look like when you take it out?</p> <p>24 MS. JONES: Objection, Your Honor, relevance and 25 previous rulings on it.</p>	<p style="text-align: center;">Page 148</p> <p>1 A. It does.</p> <p>2 Q. And what I want to do is to turn your attention to the 3 last page --</p> <p>4 MS. FITZPATRICK: First of all, Your Honor, we would 5 move this exhibit into evidence, 90001A, plaintiffs' exhibit.</p> <p>6 MS. JONES: I do have an objection. I don't have any 7 objection to Dr. Blaivas testifying about it, but I believe 8 the introduction of his report and his notes at this point is 9 cumulative and would be inappropriate.</p> <p>10 THE COURT: Let me see it.</p> <p>11 (Pause.)</p> <p>12 THE COURT: I will sustain the objection except he 13 certainly -- as to the exhibit. He certainly may testify. I 14 know that his findings -- that most of the proposed exhibit 15 was simply a recitation of the history that she gave him which 16 is already in evidence in a more original form with the 17 physicians who performed those procedures.</p> <p>18 MS. FITZPATRICK: That's right, Your Honor. I only 19 actually want to use the last page that has his documented 20 findings on it.</p> <p>21 THE COURT: You may do that. It may be admitted.</p> <p>22 MS. FITZPATRICK: Thank you, Your Honor.</p> <p>23 THE COURT: You straighten that out with the 24 Courtroom Deputy.</p> <p>25 MS. FITZPATRICK: Certainly, Your Honor, I will do</p>
<p style="text-align: center;">Page 147</p> <p>1 THE COURT: I'm assuming -- well, I'll be able to 2 deal with this with the jury. Go ahead and answer the 3 question.</p> <p>4 THE WITNESS: Well, it's very variable. It's, for 5 practical purposes, the nonexposed part, that is the part that 6 they dissect out, is always encased in scar, it's almost 7 always very, very difficult to remove, and the consistency of 8 it, to the touch and feel, is dramatically different than when 9 it was put in. It's usually firmer, thicker, harder, stuff 10 like that.</p> <p>11 BY MS. FITZPATRICK:</p> <p>12 Q. Now, Doctor, I want to turn back to your pelvic exam of 13 Mrs. Huskey. You did that on March 18th of 2014, correct?</p> <p>14 A. Yes.</p> <p>15 MS. FITZPATRICK: May I approach, Your Honor?</p> <p>16 THE COURT: You may.</p> <p>17 BY MS. FITZPATRICK:</p> <p>18 Q. And just showing you a document that has been marked 19 90001A, do you see that, Doctor?</p> <p>20 A. I do.</p> <p>21 Q. And can you tell the jury what that is?</p> <p>22 A. That's -- that's a summary of -- or recording of my 23 independent medical examination of Mrs. Huskey.</p> <p>24 Q. Okay. And does the first part of that include the 25 history that you took from Mrs. Huskey?</p>	<p style="text-align: center;">Page 149</p> <p>1 that.</p> <p>2 (PLAINTIFFS' EXHIBIT P-90001A WAS RECEIVED IN EVIDENCE.)</p> <p>3 BY MS. FITZPATRICK:</p> <p>4 Q. Dr. Blaivas, turning to the last page of your report, 5 under the section headed "PE," are those your own conclusions 6 from the physical examination that you did of Mrs. Huskey?</p> <p>7 A. They are.</p> <p>8 Q. And can you explain to the jury what you were able to 9 determine from the pelvic exam that you did of Mrs. Huskey?</p> <p>10 A. Well, the most important finding is that there was a 11 two-centimeter thick, which is about the size of my index 12 finger, scar and mass -- well, something about the size of my 13 index finger, that's what -- that's the dimension of it.</p> <p>14 Q. Are you talking across the width?</p> <p>15 A. No, from the first knuckle to the end. There is -- 16 that's the size of what I felt, and I felt it on what's called 17 the posterior lateral wall, which is really hard to describe 18 in words. But if -- so I don't think I'll try.</p> <p>19 Q. Well, let me do this, Doctor.</p> <p>20 A. Yeah.</p> <p>21 Q. Did you help me prepare a demonstrative slide that you 22 believe depicts what you found on the pelvic exam for 23 Mrs. Huskey?</p> <p>24 A. I did.</p> <p>25 Q. And does that slide accurately represent what's reflected</p>

<p style="text-align: center;">Page 150</p> <p>1 in your notes here from your exam in March of 2014?</p> <p>2 A. It does.</p> <p>3 MS. FITZPATRICK: I'm going to ask you if we can</p> <p>4 display that to the jury, Your Honor.</p> <p>5 MS. JONES: I have no objection to this being</p> <p>6 published if it's -- as a demonstrative.</p> <p>7 MS. FITZPATRICK: That's correct, Your Honor.</p> <p>8 THE COURT: You may use it as a demonstrative</p> <p>9 exhibit.</p> <p>10 MS. FITZPATRICK: Okay.</p> <p>11 (The document was published to the jury.)</p> <p>12 MS. FITZPATRICK: I don't know if I have a pointer.</p> <p>13 Do we have one? It doesn't work on the plasma.</p> <p>14 Your Honor, would it be okay for Dr. Blaivas to step</p> <p>15 down just so he can point out certain things to the jury?</p> <p>16 Apparently, the pointer doesn't work.</p> <p>17 THE COURT: You may do that, Dr. Blaivas, but I'd ask</p> <p>18 you to go to the far side of the screen, and face back this</p> <p>19 way so the court reporter can see you, and I'm sure you're</p> <p>20 experienced in these matters, but would you please speak up so</p> <p>21 everybody can hear you.</p> <p>22 BY MS. FITZPATRICK:</p> <p>23 Q. Okay, Dr. Blaivas, before we get into a description of</p> <p>24 what you found, can you orient the jury -- and I always have a</p> <p>25 problem -- what's the patient's left side and what's the</p>	<p style="text-align: center;">Page 152</p> <p>1 comes out. And then this is the -- this is the vaginal</p> <p>2 opening. And what I felt is a thin scar which was slightly</p> <p>3 tender, all along where you see in white, but then when we got</p> <p>4 to what's called the posterior lateral wall, which is over</p> <p>5 here, there was that thickened thing about the size of the tip</p> <p>6 of my finger that, with just very, very light pressure, was</p> <p>7 very tender, so tender that I decided not to push any harder.</p> <p>8 And when I did that, she was -- you could see she was visibly</p> <p>9 in pain, and that pain did not abate. It didn't go away when</p> <p>10 I took my finger out, and she was visibly in pain for -- in my</p> <p>11 office for quite a long time afterwards.</p> <p>12 Q. Let's -- let's start on Mrs. Huskey's right side. Is</p> <p>13 that the side that the tape had been eroded?</p> <p>14 A. No, it was eroded on the left.</p> <p>15 Q. Okay. So which -- I thought that the more extensive</p> <p>16 dissection had happened on her left side. Am I incorrect in</p> <p>17 that?</p> <p>18 A. That's correct.</p> <p>19 Q. Okay. So can you show us where that more extensive</p> <p>20 dissection took place?</p> <p>21 A. It would have been in here -- not would have been. It</p> <p>22 was. The extensive dissection went, again, from here all the</p> <p>23 way to the side wall over here.</p> <p>24 Q. Okay. And then on the other side, that was the side that</p> <p>25 was less dissected?</p>
<p style="text-align: center;">Page 151</p> <p>1 patient's right side in this picture?</p> <p>2 A. That's the left, and that's the right. (Indicating.)</p> <p>3 Q. So Mrs. Huskey's left side is on our right side and her</p> <p>4 right side is on our left side, we're switched around, right?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. So is this -- is this an image looking up from her</p> <p>7 feet directly?</p> <p>8 A. Exactly, as if you were standing between her legs.</p> <p>9 Q. Okay. And if you can explain to the jury, first of all,</p> <p>10 what the blue at the top is? You might want to point it out.</p> <p>11 It's a little hard to see.</p> <p>12 A. Okay. So -- excuse me a moment. This is the -- the blue</p> <p>13 is the course of the sling. So before they took -- actually,</p> <p>14 this is with the sling removed. So these are the arms of the</p> <p>15 sling.</p> <p>16 Dr. Siddique -- the sling originally went from here all</p> <p>17 the way across to here. So what Dr. Siddique did was he cut</p> <p>18 it off here and he cut it off here, and now that's gone. And</p> <p>19 what I felt is now this -- this is the vaginal opening here.</p> <p>20 And what I could feel --</p> <p>21 Q. Can you show the jury where the urethra is on that</p> <p>22 picture?</p> <p>23 A. The urethra is -- this is the pubic bone. This is -- you</p> <p>24 can all feel it in your lower belly, that's the pubic bone.</p> <p>25 And then right below here is the urethra, where the urine</p>	<p style="text-align: center;">Page 153</p> <p>1 A. It didn't require hardly anything. That was just cut.</p> <p>2 Q. Okay. Did you notice a difference in the scar on the</p> <p>3 right side versus the scar on the left side?</p> <p>4 A. Yes. The scar on the right side was just a little bit</p> <p>5 thicker than what I would say is normal scar. There was a</p> <p>6 little bit of irregularity but nothing that I would have made</p> <p>7 a particular note out of.</p> <p>8 On the left side, it was just striking. It was thick</p> <p>9 and -- thick, and the word we use is "indurated." It should</p> <p>10 be supple like you push in -- you touch your lip, it's soft.</p> <p>11 This was not soft. It was firm and just seemed to me, I mean,</p> <p>12 the clinical impression, which is different than what it was</p> <p>13 like under the microscope, but clinically I thought it was</p> <p>14 just chronically inflamed, inflammation.</p> <p>15 Q. Okay. And I'm going to come back to that in a minute,</p> <p>16 but can you tell the jury what you were able to determine</p> <p>17 about this scar that was near the urethra?</p> <p>18 A. That it was -- it was a bit nodular and -- nodular --</p> <p>19 nodular means little bumps, and slightly tender.</p> <p>20 Q. And when you're talking about these findings that you had</p> <p>21 from the physical exam, are these objective findings, Doctor?</p> <p>22 A. I mean, they're as objective as one single person can be,</p> <p>23 yes.</p> <p>24 Q. And -- but the feeling of firmness or the scar tissue,</p> <p>25 that was an objective finding by you. You weren't relying on</p>

<p style="text-align: center;">Page 154</p> <p>1 Mrs. Huskey's description for that, were you?</p> <p>2 A. I don't think she even knew it was there.</p> <p>3 Q. Okay. And when you say that Mrs. Huskey was visibly in</p> <p>4 pain, do you -- in your experience in dealing with women who</p> <p>5 have pelvic floor issues, do you have the occasion to view</p> <p>6 your patients regularly as to how they react to pain?</p> <p>7 A. I do. I make a special note of that, actually.</p> <p>8 Q. And do you have an opinion to a reasonable degree of</p> <p>9 medical certainty, based on your interactions with Mrs. Huskey</p> <p>10 and based on the findings of your exam, whether she was</p> <p>11 exaggerating in any way the pain that she was experiencing</p> <p>12 upon your examination?</p> <p>13 MS. JONES: Objection, Your Honor.</p> <p>14 THE COURT: I'll allow him to offer his observation.</p> <p>15 THE WITNESS: No, I do not think she was</p> <p>16 exaggerating.</p> <p>17 BY MS. FITZPATRICK:</p> <p>18 Q. Okay.</p> <p>19 A. I'm confident that she wasn't.</p> <p>20 Q. And unless you have something else you're going to point</p> <p>21 out there, we can put you back on the witness stand for now.</p> <p>22 A. All right.</p> <p>23 Q. And, Doctor, do you have an opinion to a reasonable</p> <p>24 degree of medical certainty on the cause of the abnormal</p> <p>25 pelvic findings you determined in Mrs. Huskey's examination?</p>	<p style="text-align: center;">Page 155</p> <p>1 MS. JONES: Objection, Your Honor.</p> <p>2 THE COURT: Overruled.</p> <p>3 THE WITNESS: Yes, I do.</p> <p>4 BY MS. FITZPATRICK:</p> <p>5 Q. Okay. And what is that opinion, Doctor?</p> <p>6 A. That it was caused by the scarring from the mesh removal.</p> <p>7 Q. Okay. And was there -- well, let me ask you this,</p> <p>8 Dr. Blaivas. You work with women who have mesh complications.</p> <p>9 Have you seen other patients with similar scarring and</p> <p>10 tenderness to Mrs. Huskey?</p> <p>11 A. Yes, I have.</p> <p>12 MS. JONES: Objection, relevance.</p> <p>13 THE COURT: Just one second.</p> <p>14 (Pause.)</p> <p>15 THE COURT: I will allow that question and that</p> <p>16 answer.</p> <p>17 MS. FITZPATRICK: Thank you, Your Honor.</p> <p>18 BY MS. FITZPATRICK:</p> <p>19 Q. Dr. Blaivas, I had asked you in your work with women who</p> <p>20 have mesh complications whether you had ever seen patients</p> <p>21 with similar scarring and tenderness to what you found in</p> <p>22 Mrs. Huskey.</p> <p>23 A. Yes, I have.</p> <p>24 Q. And have you ever seen that presentation, that type of</p> <p>25 abnormal finding, in patients who have not had a mesh removal</p> <p style="text-align: center;">Page 156</p> <p>1 surgery?</p> <p>2 A. I have not.</p> <p>3 Q. Is there -- in your opinion, to a reasonable degree of</p> <p>4 medical certainty, is there any other medical condition or</p> <p>5 surgery that can cause this kind of abnormal pelvic finding?</p> <p>6 MS. JONES: Objection, Your Honor.</p> <p>7 THE COURT: Overruled.</p> <p>8 THE WITNESS: None that I know of.</p> <p>9 BY MS. FITZPATRICK:</p> <p>10 Q. Now, Doctor, do you have an opinion, to a reasonable</p> <p>11 degree of medical certainty, as to whether Mrs. Huskey is</p> <p>12 suffering from chronic pelvic pain?</p> <p>13 A. I do.</p> <p>14 Q. And what is that opinion?</p> <p>15 A. That she is suffering from chronic pelvic pain.</p> <p>16 Q. And do you have an opinion, again, to a reasonable degree</p> <p>17 of medical certainty, whether the vaginal findings that you</p> <p>18 just identified for us are a cause of the chronic pelvic pain</p> <p>19 that Mrs. Huskey is experiencing?</p> <p>20 A. I'm quite confident that there is --</p> <p>21 MS. JONES: Objection.</p> <p>22 THE COURT: Overruled.</p> <p>23 MS. FITZPATRICK: I'm sorry, Doctor, go ahead.</p> <p>24 THE WITNESS: I said I'm quite confident that --</p> <p>25 that -- now I forget the question, but I remember the answer.</p>
<p style="text-align: center;">Page 155</p> <p>1 MS. JONES: Objection, Your Honor.</p> <p>2 THE COURT: Overruled.</p> <p>3 THE WITNESS: Yes, I do.</p> <p>4 BY MS. FITZPATRICK:</p> <p>5 Q. Okay. And what is that opinion, Doctor?</p> <p>6 A. That it was caused by the scarring from the mesh removal.</p> <p>7 Q. Okay. And was there -- well, let me ask you this,</p> <p>8 Dr. Blaivas. You work with women who have mesh complications.</p> <p>9 Have you seen other patients with similar scarring and</p> <p>10 tenderness to Mrs. Huskey?</p> <p>11 A. Yes, I have.</p> <p>12 MS. JONES: Objection, relevance.</p> <p>13 THE COURT: Just one second.</p> <p>14 (Pause.)</p> <p>15 THE COURT: I will allow that question and that</p> <p>16 answer.</p> <p>17 MS. FITZPATRICK: Thank you, Your Honor.</p> <p>18 BY MS. FITZPATRICK:</p> <p>19 Q. Dr. Blaivas, I had asked you in your work with women who</p> <p>20 have mesh complications whether you had ever seen patients</p> <p>21 with similar scarring and tenderness to what you found in</p> <p>22 Mrs. Huskey.</p> <p>23 A. Yes, I have.</p> <p>24 Q. And have you ever seen that presentation, that type of</p> <p>25 abnormal finding, in patients who have not had a mesh removal</p>	<p style="text-align: center;">Page 157</p> <p>1 Can you repeat the question?</p> <p>2 BY MS. FITZPATRICK:</p> <p>3 Q. Sure. Let me see if I can get this right.</p> <p>4 Do you have an opinion, to a reasonable degree of</p> <p>5 medical certainty, whether the vaginal -- the abnormal pelvic</p> <p>6 findings that you determined Mrs. Huskey to have are a cause</p> <p>7 of her chronic pelvic pain?</p> <p>8 A. I do.</p> <p>9 Q. Okay. And what is that opinion?</p> <p>10 A. That it -- that they are a cause -- or it is a cause.</p> <p>11 Q. Okay. In fact, Doctor, you have actually published some</p> <p>12 articles on the subject of mesh complications that require</p> <p>13 surgery, have you not?</p> <p>14 A. I have.</p> <p>15 MS. FITZPATRICK: May I approach, Your Honor?</p> <p>16 THE COURT: You may.</p> <p>17 BY MS. FITZPATRICK:</p> <p>18 Q. Okay, Doctor, I have just shown you an exhibit, Number</p> <p>19 20176. Do you see that?</p> <p>20 A. I do.</p> <p>21 Q. And can you identify that for me?</p> <p>22 A. Yes. It's a paper that I published on -- on mesh</p> <p>23 complications.</p> <p>24 Q. Okay. And can you tell the jury what the title of that</p> <p>25 article -- actually --</p>

<p style="text-align: center;">Page 158</p> <p>1 A. "Salvage Surgery After Failed Treatment of Synthetic Mesh 2 Sling Complications."</p> <p>3 MS. FITZPATRICK: Your Honor, at this point I would 4 like to move the introduction of 20176 into evidence.</p> <p>5 MS. JONES: Object, Your Honor, as to moving it into 6 evidence as to 803.18. If she wants to publish it to the 7 jury, I have no problem.</p> <p>8 MS. FITZPATRICK: Your Honor, we'll move it in as a 9 learned treatise, as an exhibit.</p> <p>10 THE COURT: All right.</p> <p>11 (PLAINTIFFS EXHIBIT P-20176 WAS RECEIVED IN EVIDENCE.)</p> <p>12 MS. FITZPATRICK: And may I publish this to the jury, 13 Your Honor?</p> <p>14 THE COURT: You may, in conjunction with his 15 testimony.</p> <p>16 (The document was published to the jury.)</p> <p>17 BY MS. FITZPATRICK:</p> <p>18 Q. Okay. Dr. Blaivas, you were telling us the title of your 19 article. Can you tell the jury what that is?</p> <p>20 A. I just did, didn't I?</p> <p>21 Q. Well, you probably did, and I didn't hear it. I 22 apologize.</p> <p>23 A. "Salvage Surgery After Failed Treatment of Synthetic Mesh 24 Sling Complications."</p> <p>25 Q. Okay. What do you mean by "salvage surgery"?</p>	<p style="text-align: center;">Page 160</p> <p>1 different careers in medicine.</p> <p>2 Q. Okay.</p> <p>3 A. But Dr. Purohit is my associate and he works -- we work 4 together on these.</p> <p>5 THE COURT: Let me interrupt for just a minute and 6 ask a question, so that the lawyers then will have a chance to 7 ask questions and object to my question.</p> <p>8 Did I understand you to say a few minutes ago that 9 the scar firm place the size of the tip of your index finger 10 was caused by the removal procedure?</p> <p>11 THE WITNESS: You probably did, but I didn't mean 12 exactly that. It was in the course --</p> <p>13 THE COURT: You've answered my question.</p> <p>14 THE WITNESS: Okay.</p> <p>15 MS. FITZPATRICK: Well, now I'm going to have a 16 question for you.</p> <p>17 THE WITNESS: Okay.</p> <p>18 (Laughter.)</p> <p>19 BY MS. FITZPATRICK:</p> <p>20 Q. What -- did you determine what the causes of that scar 21 firmness that you detected were?</p> <p>22 A. Well, I think it's a reaction to the mesh, to the 23 inflammation of mesh, causes the scarring. It wasn't so much 24 the removal, but it's a natural -- it's one of the processes 25 by which these things cause pain, they become inflamed, and</p>
<p style="text-align: center;">Page 159</p> <p>1 A. It means doing -- it means that the patient had a sling 2 operation and then they had a second operation to remove the 3 mesh, and that didn't work, and I'm doing -- this is a series 4 of patients that I operated on that had at least one failed 5 attempt to fix their problem.</p> <p>6 Q. And is this paper -- do you -- can you tell us what year 7 this was published?</p> <p>8 A. 2013.</p> <p>9 Q. Okay. And what year was it submitted for publication, 10 Doctor? Do you know?</p> <p>11 A. Probably, I think it was the same year.</p> <p>12 Q. Okay. And what journal does this appear in?</p> <p>13 A. The Journal of Urology.</p> <p>14 Q. Okay. And is that a peer-reviewed journal?</p> <p>15 A. That has the highest, what's called, citation index.</p> <p>16 That's the most respected journal in urology.</p> <p>17 Q. Okay. And who were your co-authors on this?</p> <p>18 A. Rajveer Purohit, James Weinberger, Johnson Tsui, Jyoti 19 Chouhan, Ruhee Sidhu, Kamron Saleem.</p> <p>20 Q. And are these all people that you work with on this issue 21 of how to cure or solve or mitigate mesh-related complications 22 in women?</p> <p>23 A. Well, actually, they're all -- aside from Dr. Purohit, 24 they're all researchers. They were all doing research with 25 me, and they have all gone on to -- I mean, they've gone on to</p>	<p style="text-align: center;">Page 161</p> <p>1 then when you take them out, it can still be -- these kinds 2 of -- we call them inflammatory masses. And they can cause 3 pain. And sometimes even when you think you've removed every 4 single last bit of mesh, there can still be mesh in there. So 5 you know don't know until you take it out.</p> <p>6 THE COURT: So the answer that it was the removal 7 that caused it was incorrect, and now the answer that it was 8 the mesh you believe is the correct?</p> <p>9 THE WITNESS: That's correct.</p> <p>10 BY MS. FITZPATRICK:</p> <p>11 Q. And, Doctor, actually, I want to -- to ask you if you 12 would agree with me that the mesh, the device itself and the 13 procedure associated with that device, were causes of the 14 abnormal pelvic findings that you found?</p> <p>15 MS. JONES: Objection.</p> <p>16 THE COURT: Sustained.</p> <p>17 THE WITNESS: Yes, I do.</p> <p>18 THE COURT: Overruled. I mean sustained. Disregard 19 it, please.</p> <p>20 MS. FITZPATRICK: Okay.</p> <p>21 BY MS. FITZPATRICK:</p> <p>22 Q. Were there other causes besides just the mesh device 23 itself?</p> <p>24 THE COURT: Causes of what?</p> <p>25 MS. FITZPATRICK: Causes of the -- okay. Let me try</p>

<p style="text-align: center;">Page 162</p> <p>1 this again, Your Honor.</p> <p>2 BY MS. FITZPATRICK:</p> <p>3 Q. Were -- in your opinion, Doctor, were there other causes</p> <p>4 of the abnormal pelvic findings that you saw in Mrs. Huskey,</p> <p>5 besides simply the mesh device itself?</p> <p>6 A. No.</p> <p>7 Q. Did the procedures have anything to do with your</p> <p>8 findings? The mesh-related procedures, to clarify.</p> <p>9 A. Well, yes. I think when -- the answer is yes.</p> <p>10 Q. Okay. Let me go back to your article on salvage surgery.</p> <p>11 And is this consistent with your opinions and your findings in</p> <p>12 Mrs. Huskey's specific case?</p> <p>13 A. I'm sorry. I don't understand the question.</p> <p>14 MS. FITZPATRICK: Let me pull up 1282 first -- first</p> <p>15 column, first full paragraph, 1282, Page 1282. Thank you.</p> <p>16 (The document was published to the jury.)</p> <p>17 BY MS. FITZPATRICK:</p> <p>18 Q. You write here, Doctor, "That the management of mesh</p> <p>19 sling complications is fraught with complexity, and even in</p> <p>20 the most experienced hands the outcomes are suboptimal."</p> <p>21 Do you believe that that's consistent with your</p> <p>22 findings in Mrs. Huskey's specific case?</p> <p>23 A. Absolutely, yes.</p> <p>24 Q. And I want to turn your attention to Page 1283, second</p> <p>25 column, where it starts "nevertheless."</p>	<p style="text-align: center;">Page 164</p> <p>1 MS. JONES: Objection, Your Honor. Can we approach?</p> <p>2 THE COURT: You may.</p> <p>3 (The following occurred at sidebar.)</p> <p>4 THE COURT: First of all, I sustain the objection as</p> <p>5 to the question about mesh cripples, under 403. It's totally</p> <p>6 prejudicial. I don't think I can find it in the medical book.</p> <p>7 Now, what did you all want to talk about?</p> <p>8 MS. FITZPATRICK: I don't think that was the answer</p> <p>9 to the question.</p> <p>10 MS. JONES: That was one of them.</p> <p>11 But the second thing is, Your Honor, in the Daubert</p> <p>12 ruling, I think you specifically excluded his testimony about</p> <p>13 the increasing -- the alleged increasing number of injuries.</p> <p>14 I'm just -- I'm looking for it.</p> <p>15 MS. FITZPATRICK: Well, Your Honor, I'm going to pull</p> <p>16 this slide down which is the only place that that's</p> <p>17 referenced.</p> <p>18 THE COURT: Okay.</p> <p>19 MS. FITZPATRICK: I think that takes care of it.</p> <p>20 THE COURT: All right.</p> <p>21 (Sidebar concluded.)</p> <p>22 MS. FITZPATRICK: Okay. Can you turn the Page 1285</p> <p>23 of that same article, please. And if you can pull up the</p> <p>24 first two sentences of the first full paragraph in the second</p> <p>25 column.</p>
<p style="text-align: center;">Page 163</p> <p>1 You say here that "Nevertheless, we do believe that</p> <p>2 there is a small cohort of patients whose lives have been</p> <p>3 unalterably changed for the worse as a complication of these</p> <p>4 seemingly trivial and easy-to-perform operations."</p> <p>5 What operations are you talking about there?</p> <p>6 A. The synthetic mesh slings.</p> <p>7 Q. Do you believe that Mrs. Huskey is one of the cohort of</p> <p>8 patients whose lives have been unalterably changed for the</p> <p>9 worse?</p> <p>10 MS. JONES: Objection.</p> <p>11 THE COURT: I think sustained. I not only think</p> <p>12 sustained, I will sustain.</p> <p>13 BY MS. FITZPATRICK:</p> <p>14 Q. Is this consistent with your opinions in Mrs. Huskey's</p> <p>15 specific case?</p> <p>16 A. Yes, it is.</p> <p>17 MS. FITZPATRICK: And then if you can turn to Page</p> <p>18 1284 and just pull out that small paragraph that's -- yeah,</p> <p>19 right there, if you can pull that out. Okay.</p> <p>20 BY MS. FITZPATRICK:</p> <p>21 Q. You say here that "We believe that there will be an</p> <p>22 increasing number of patients in whom initial treatments</p> <p>23 failed, an increasing number of mesh cripples."</p> <p>24 What do you mean by "mesh cripples"?</p> <p>25 A. Mesh --</p>	<p style="text-align: center;">Page 165</p> <p>1 (The document was published to the jury.)</p> <p>2 BY MS. FITZPATRICK:</p> <p>3 Q. And here you note in this article, Doctor, that "Pelvic</p> <p>4 pain and dyspareunia pose particularly difficult challenges,</p> <p>5 and despite our best efforts, treatment was unsuccessful in</p> <p>6 half of the patients."</p> <p>7 Is treatment to date for Mrs. Huskey, for pelvic pain</p> <p>8 and dyspareunia, is it unsuccessful?</p> <p>9 A. It is.</p> <p>10 Q. And is that consistent with your conclusions and findings</p> <p>11 in your research?</p> <p>12 A. It is.</p> <p>13 Q. And, Doctor, are there other articles besides the ones</p> <p>14 that you have published in the scientific and medical</p> <p>15 literature that discuss the types of serious complications</p> <p>16 that we've been discussing today?</p> <p>17 A. Yes, there are.</p> <p>18 Q. And let me --</p> <p>19 MS. FITZPATRICK: If I may approach, Your Honor?</p> <p>20 THE COURT: You may.</p> <p>21 BY MS. FITZPATRICK:</p> <p>22 Q. And, Doctor, if you can take a look at the article that I</p> <p>23 gave you that's Exhibit Number 20178. Can you identify that</p> <p>24 document for the jury?</p> <p>25 A. Yes.</p>

<p style="text-align: center;">Page 166</p> <p>1 Q. Okay. And is this an article that you relied on, in 2 part, for your opinions in this case?</p> <p>3 A. It supports my opinions, yes.</p> <p>4 Q. Doctor --</p> <p>5 MS. FITZPATRICK: Judge --</p> <p>6 THE COURT: Nothing -- that's not enough.</p> <p>7 BY MS. FITZPATRICK:</p> <p>8 Q. Dr. Blaivas, did you review this article in connection 9 with the opinions that you gave in this case?</p> <p>10 A. I did.</p> <p>11 Q. And does it form part of the basis of your opinions in 12 this case?</p> <p>13 A. Yes, it does.</p> <p>14 MS. FITZPATRICK: Your Honor, I would like to move 15 this in as a learned treatise, please.</p> <p>16 MS. JONES: Judge, I have an objection to those.</p> <p>17 THE COURT: Do you want to do it over here?</p> <p>18 Now, this is when you all should stand up and 19 stretch.</p> <p>20 (The following occurred at sidebar.)</p> <p>21 THE COURT: Yes, ma'am.</p> <p>22 MS. JONES: Your Honor, my objection to this is I 23 don't believe it's qualified as an appropriate foundation laid 24 for this article as a learned treatise. It, in fact, is a 25 collaborative editorial which amounts to, if you will, opinion</p>	<p style="text-align: center;">Page 168</p> <p>1 (Sidebar concluded.)</p> <p>2 BY MS. FITZPATRICK:</p> <p>3 Q. Now, Doctor, can you take a look at what has been marked 4 as Plaintiffs' Exhibit 20180.</p> <p>5 A. Yes.</p> <p>6 Q. Okay. And can you identify that for the jury?</p> <p>7 A. "Symptom Resolution After Operative Management of 8 Complications From Transvaginal Mesh."</p> <p>9 Q. And who are the authors on that?</p> <p>10 A. Erin Crosby, Melinda Abernethy, Mitchell Berger, John 11 DeLancey, Dee Fenner, and Daniel Morgan.</p> <p>12 Q. And is this a published article in a peer-reviewed 13 journal considering -- or concerning original research that 14 had been done by these authors?</p> <p>15 A. It is.</p> <p>16 Q. Okay. And what year was it published?</p> <p>17 A. 2014.</p> <p>18 Q. And where was it published?</p> <p>19 A. In <i>Obstetrics and Gynecology</i> is the name of the journal.</p> <p>20 Q. And do you find that journal to be authoritative?</p> <p>21 A. It's a very reputable journal.</p> <p>22 Q. And is this an article that you relied on in forming the 23 basis for your opinions in Mrs. Huskey's case here?</p> <p>24 A. It is.</p> <p>25 MS. FITZPATRICK: Your Honor, I'd like to move this</p>
<p style="text-align: center;">Page 167</p> <p>1 testimony -- or opinion.</p> <p>2 THE COURT: Tell me a little --</p> <p>3 MS. JONES: Not testimony.</p> <p>4 THE COURT: All right. Tell me a little bit about 5 it, Ms. Fitzpatrick.</p> <p>6 MS. FITZPATRICK: Your Honor, it is a collaborative 7 editorial that was published by a number of people who 8 specialize in mesh removal surgery. And what it is is it's 9 based on -- and footnoted and cited, so it's not simply just 10 opinions, to the conclusions that they have reached concerning 11 the complications that arise in mesh and the intractability of 12 those particular complications. It comes complete with 13 references and it's something that Dr. Blaivas has looked at 14 and has relied on and finds to be authoritative and supporting 15 the opinions that he has reached in this case.</p> <p>16 THE COURT: I think you make about as articulate and 17 as good an argument for that as I think you can.</p> <p>18 MS. FITZPATRICK: Thank you, Judge, I'm trying.</p> <p>19 THE COURT: On the other hand, I'm not going to be 20 the person who extends the learned treatise exception to 21 editorials.</p> <p>22 MS. FITZPATRICK: Okay.</p> <p>23 THE COURT: So I will sustain the objection.</p> <p>24 MS. FITZPATRICK: I tried. Give me points for 25 trying.</p>	<p style="text-align: center;">Page 169</p> <p>1 into evidence as a learned treatise.</p> <p>2 THE COURT: Maybe -- yes.</p> <p>3 MS. JONES: Your Honor, I do have an objection. Not 4 only -- not on the grounds of a learned treatise, but on the 5 grounds that it's irrelevant because it does not deal with 6 midurethral slings in the -- it's a different type of 7 treatment altogether.</p> <p>8 THE COURT: Well, I guess we've got to jump back over 9 here for a minute. Let me look at it.</p> <p>10 (The following occurred at sidebar.)</p> <p>11 MS. FITZPATRICK: This was -- the purpose for this 12 was to talk about removal of mesh and the symptom resolution 13 for patients who have removal of mesh surgery.</p> <p>14 MS. JONES: And, Your Honor, I object to it on the 15 grounds of relevance and on the grounds of 403, on the grounds 16 that this deals very specifically with complications from 17 transvaginal mesh placed for prolapse and not for stress 18 urinary incontinence, and those are different products placed 19 in a different manner and in a different way, and to the 20 extent that it has any probative value whatsoever, it is 21 outweighed by the prejudice and confusion.</p> <p>22 THE COURT: The foundation made by plaintiffs' 23 counsel was textbook. The answer was that he did rely on it. 24 I think it's proper to use it, and, apparently, you have a 25 very fertile field for cross-examination.</p>

<p style="text-align: center;">Page 170</p> <p>1 MS. FITZPATRICK: Thank you, Judge. 2 (Sidebar concluded.) 3 (PLAINTIFFS' EXHIBIT P-2018- WAS RECEIVED IN EVIDENCE.) 4 BY MS. FITZPATRICK: 5 Q. Doctor, taking a look at Plaintiffs' Exhibit 20180 that's 6 in front of you, am I correct in that this article deals with 7 transvaginal mesh that has been placed for prolapse repair? 8 A. Yes, you are. 9 Q. And are those products made with the same material that 10 the transvaginal mesh slings are made from? 11 A. Yes. 12 Q. But they treat a different condition, correct? 13 A. Yes. 14 Q. And they're placed differently? 15 A. They're placed in different places and they use slightly 16 different instruments, but it's the -- it's the -- it's 17 similar. 18 Q. And they actually contain more mesh than the slings, 19 correct? 20 A. Correct. 21 Q. What is it about this article that you relied on, given 22 that it does deal with these prolapse products instead of the 23 SUI products? 24 A. Because their reactions are the same. I mean, the way 25 the body -- one of the issues is the way the body scars, for</p>	<p>1 Q. Based on your experience, Doctor, do these types of 2 serious complications that we've been discussing occur even 3 when -- even when experienced surgeons implant these 4 polypropylene midurethral slings? 5 MS. JONES: Objection. 6 THE COURT: Sustained. 7 THE WITNESS: I'm sorry? 8 THE COURT: Sustained. 9 THE WITNESS: Yes -- 10 THE COURT: Wait. Sustained means -- 11 THE WITNESS: Oh, sustained, okay. 12 BY MS. FITZPATRICK: 13 Q. And have you seen serious complications arise from the 14 use of polypropylene -- I'm going to actually make it 15 transobturator slings, when the device is placed properly 16 following the manufacturer's instructions? 17 MS. JONES: Objection, Your Honor. 18 THE COURT: Overruled. 19 THE WITNESS: Yes, I have. 20 BY MS. FITZPATRICK: 21 Q. And have you seen serious complications arise from the 22 use of transobturator polypropylene slings when experienced 23 surgeons have implanted these devices? 24 MS. JONES: Objection. 25 THE COURT: Overruled.</p>
<p style="text-align: center;">Page 171</p> <p>1 lack of a better word, around these things, and that's the 2 same. 3 Q. And I want to direct your attention to the conclusions in 4 this article which are on Page 134. That's at the bottom of 5 the first column, the top of the second column. 6 (The document was published to the jury.) 7 BY MS. FITZPATRICK: 8 Q. Okay. And the conclusion of these authors was that 9 "Removal of vaginal mesh is helpful in relieving symptoms of 10 presentation. Patients can be reassured that exposed mesh can 11 almost always be successfully managed surgically, but pain and 12 dyspareunia are only resolved completely in half of these 13 patients." 14 How does this reflect your experience in surgically 15 treating and managing women who have complications from 16 polypropylene midurethral slings? 17 A. It's -- I mean, it's analogous. It's the same problem. 18 I mean, you can remove the sling, can remove all the visible 19 mesh, if you will, and the symptoms persist. And, 20 particularly, in Mrs. Huskey's case, that appears to be what 21 happened. It appears that the sling was removed successfully, 22 although we don't know for sure if there's any mesh left in 23 what I felt, but her symptoms persist and, if anything -- and, 24 excuse me, and her symptoms persist, so it's exactly the same 25 as this.</p>	<p style="text-align: center;">Page 173</p> <p>1 THE WITNESS: Yes, I've seen them from the most 2 famous surgeons in the world. 3 BY MS. FITZPATRICK: 4 Q. Okay. Now, let's get back to Mrs. Huskey and your 5 findings on Mrs. Huskey's exam. 6 What are any other reasons, besides the TTV-O devices 7 and the procedures that we talked about, why Mrs. Huskey could 8 be presenting with this type of vaginal examination? 9 A. Well, I don't know of anything else that can cause this 10 particular type of examination, this particular constellation 11 of symptoms. 12 Q. Okay. Now, what's your basis for that opinion? 13 A. You know, to a large extent, you know, 35 years of 14 experience with these things. I just -- until mesh came 15 along, I never felt things like this. 16 Q. And could the abnormal pelvic exam -- could Mrs. Huskey's 17 abnormal pelvic exam be the result in any way of a dysfunction 18 in her sacroiliac joint? 19 A. I don't believe so. 20 Q. Why not? 21 A. Because it doesn't cause these symptoms. 22 Q. What -- the sacroiliac joint does not cause these 23 symptoms? 24 A. Correct. 25 Q. And could Mrs. Huskey's abnormal pelvic exam be a result</p>

<p style="text-align: center;">Page 174</p> <p>1 of complications arising from diverticulosis or 2 diverticulitis -- diverticulitis?</p> <p>3 A. No.</p> <p>4 Q. Is that even a possibility?</p> <p>5 MS. JONES: Objection.</p> <p>6 THE WITNESS: I would say no. I mean, I hate to -- 7 no, it's a no. I can't think of a reason it could be.</p> <p>8 BY MS. FITZPATRICK:</p> <p>9 Q. And could Mrs. Huskey's abnormal pelvic exam be the 10 result of an ovarian cyst?</p> <p>11 A. No.</p> <p>12 Q. Okay. Is an ovarian cyst even in the same area --</p> <p>13 A. No.</p> <p>14 Q. -- that Mrs. Huskey is experiencing this pain?</p> <p>15 A. No, it's not.</p> <p>16 Q. Okay. Is the large intestines even in the area where 17 Mrs. Huskey is experiencing this pain and has these findings?</p> <p>18 A. Not -- not these pain -- not this constellation of 19 symptoms, no.</p> <p>20 Q. Okay. And is the SI joint in the area where Mrs. Huskey 21 is having this pain and this constellation of symptoms, as you 22 call it?</p> <p>23 A. No.</p> <p>24 Q. Can you rule these alternate causes out to a reasonable 25 degree of medical certainty?</p>	<p style="text-align: center;">Page 176</p> <p>1 examination?</p> <p>2 A. No.</p> <p>3 Q. Is your finding on examination -- let me ask it this way: 4 Are there any reports in the medical records on pelvic and 5 left lower quadrant pain that are in any way related to your 6 abnormal pelvic findings upon examination?</p> <p>7 A. No.</p> <p>8 Q. Is there any report in her medical records of pelvic or 9 left lower quadrant pain that is the cause of her current or 10 is related to her current chronic pelvic pain?</p> <p>11 A. No.</p> <p>12 Q. Are there any reports or any medical records concerning 13 back pain that could be a cause or related to the abnormal 14 pelvic findings that you saw on Mrs. Huskey's examination?</p> <p>15 A. No.</p> <p>16 Q. Are there any reports of back pain that could be related 17 to the chronic pelvic pain that Mrs. Huskey is currently 18 experiencing?</p> <p>19 A. No.</p> <p>20 Q. Can you tell the jury what vaginitis is?</p> <p>21 A. It's inflammation of the vagina.</p> <p>22 Q. Okay. Are there any reports in the medical records prior 23 to February 22nd, 2011, of vaginitis?</p> <p>24 A. I'm sorry. Prior to what date?</p> <p>25 Q. The implant of the TVT-O on February 23rd, 2011.</p>
<p style="text-align: center;">Page 175</p> <p>1 A. I would say with a very high degree of certainty, yes.</p> <p>2 Q. Okay. I want to show you a demonstrative.</p> <p>3 MS. FITZPATRICK: I'd like to show this to the jury.</p> <p>4 MS. JONES: Okay.</p> <p>5 (The document was published to the jury.)</p> <p>6 MS. FITZPATRICK: Well, I'm not going to be able to 7 read that. But -- let me take -- well, I've got a copy here.</p> <p>8 BY MS. FITZPATRICK:</p> <p>9 Q. Now, this is a summary that was prepared for opening 10 about Mrs. Huskey's prior medical records, and this was prior 11 to the TVT-O implant. And I want to ask you, Doctor, a series 12 of questions to a reasonable degree of medical certainty.</p> <p>13 Is any diagnosis of stress and depression prior to 14 February 23rd, 2011, a cause of the abnormal pelvic findings 15 that you saw in Mrs. Huskey?</p> <p>16 A. No.</p> <p>17 Q. Is it a cause of the chronic pain that Mrs. Huskey -- 18 chronic pelvic pain that Mrs. Huskey is currently 19 experiencing?</p> <p>20 A. No.</p> <p>21 Q. Looking at abdominal pain and suprapubic pain, are there 22 any reports in the medical literature -- not the medical 23 literature -- her medical records of any kind of abdominal 24 pain or suprapubic pain prior to the implant of this device on 25 February 23rd, 2011, that are related to your findings upon</p>	<p style="text-align: center;">Page 177</p> <p>1 A. I think there might have been. I don't have an 2 independent recollection of it now.</p> <p>3 Q. Do you remember whether that vaginitis was treated and 4 cured?</p> <p>5 A. Yes, it -- yeah, it was just a sporadic thing. It was 6 treated and got better.</p> <p>7 Q. Is there any way, in your opinion, that any diagnosis of 8 vaginitis can be a cause of the abnormal pelvic findings that 9 you determined in your exam?</p> <p>10 A. No.</p> <p>11 Q. Is there any way that the vaginitis could be a cause of 12 the chronic pelvic pain that Mrs. Huskey currently 13 experiences?</p> <p>14 A. No.</p> <p>15 Q. Pain in the left lower back and left flank, in reviewing 16 her medical records, is there any medical condition that 17 caused pain in the left lower back and left flank that could 18 cause the type of abnormal pelvic findings that you saw in 19 Mrs. Huskey's case?</p> <p>20 A. No.</p> <p>21 Q. Is there any report of pain in the left lower back and 22 left flank that could account for her current chronic pelvic 23 pain?</p> <p>24 A. No.</p> <p>25 Q. Next is vaginal itching. Is that related to the</p>

<p style="text-align: center;">Page 178</p> <p>1 vaginitis?</p> <p>2 A. Could be, yes. It's a symptom of it.</p> <p>3 Q. Is there any way that vaginal itching could cause the</p> <p>4 type of abnormal pelvic findings that you saw in Mrs. Huskey's</p> <p>5 case?</p> <p>6 A. No.</p> <p>7 Q. Is there any way that vaginal itching could cause the</p> <p>8 type of chronic pelvic pain that Mrs. Huskey is currently</p> <p>9 experiencing?</p> <p>10 A. No.</p> <p>11 Q. Small follicular cysts identified in the left ovary.</p> <p>12 That's the ovarian cyst that we previously discussed?</p> <p>13 A. Yes.</p> <p>14 Q. And then vaginal dryness, can you explain vaginal dryness</p> <p>15 to the jury, please?</p> <p>16 A. Ordinarily, there's vaginal secretions, again, like the</p> <p>17 inside -- a little bit like the inside of your lip. When you</p> <p>18 have hormone deficiency, in particular, when you're menopausal</p> <p>19 or perimenopausal, you lack estrogen and the estrogen is -- is</p> <p>20 required to keep that moisture there. So when there's a</p> <p>21 decrease in estrogen, you can get dry.</p> <p>22 Q. Okay. Is there any way that vaginal dryness could cause</p> <p>23 the type of abnormal scarring that you saw in Mrs. Huskey's</p> <p>24 pelvis?</p> <p>25 A. No.</p>	<p style="text-align: center;">Page 180</p> <p>1 BY MS. FITZPATRICK:</p> <p>2 Q. Now, you know that Mrs. Huskey went to the Emergency Room</p> <p>3 in December, 2010, correct?</p> <p>4 A. I do.</p> <p>5 Q. And in those emergency record notes, there were</p> <p>6 complaints of what was called pelvic pain, correct?</p> <p>7 A. Correct.</p> <p>8 Q. What is your understanding of the cause of that pelvic</p> <p>9 pain?</p> <p>10 A. Well, I wasn't there, but Dr. Byrkit ultimately concluded</p> <p>11 two things in her notes: One, that it was not of gynecologic</p> <p>12 origin, that it had nothing to do with the female reproductive</p> <p>13 system; and two, it was most likely related to her colon and</p> <p>14 diverticulosis.</p> <p>15 Q. Okay. Are the current -- you said that Dr. Byrkit had</p> <p>16 determined that the problems that she had in December of 2010</p> <p>17 were not gynecological in origin; is that correct?</p> <p>18 A. Correct.</p> <p>19 Q. Are her current problems gynecologic in origin?</p> <p>20 A. Yes, they are.</p> <p>21 Q. And you reviewed all of the tests and notes and</p> <p>22 everything that Mrs. Huskey underwent at that time in 2010,</p> <p>23 correct?</p> <p>24 A. I did.</p> <p>25 Q. Is there anything in those records that was consistent</p>
<p style="text-align: center;">Page 179</p> <p>1 Q. Now, vaginal dryness can cause dyspareunia, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And dyspareunia is pain with sexual intercourse?</p> <p>4 A. Yes.</p> <p>5 Q. Can vaginal dryness cause the type of dyspareunia that</p> <p>6 Mrs. Huskey is currently experiencing?</p> <p>7 A. No.</p> <p>8 Q. And can you give us your opinion, to a reasonable degree</p> <p>9 of medical certainty, whether any of these conditions that</p> <p>10 have been identified from Mrs. Huskey's medical records prior</p> <p>11 to the TVT-O implant are in any way related to the medical</p> <p>12 conditions seen here in front of this jury?</p> <p>13 A. They are not related, no.</p> <p>14 MS. FITZPATRICK: Thank you, Doctor.</p> <p>15 THE COURT: Cross-examine.</p> <p>16 MS. FITZPATRICK: Oh, I'm not done yet, Judge.</p> <p>17 THE COURT: Oh, I'm sorry.</p> <p>18 MS. FITZPATRICK: You sounded so hopeful there. I'm</p> <p>19 getting there though.</p> <p>20 (Laughter.)</p> <p>21 MS. FITZPATRICK: Perhaps you're telling me I should</p> <p>22 sit down.</p> <p>23 THE COURT: No, no, no. I just saw you packing up.</p> <p>24 MS. FITZPATRICK: I was just flipping my binder</p> <p>25 around.</p>	<p style="text-align: center;">Page 181</p> <p>1 with the abnormal exam and scar tissue that you saw?</p> <p>2 A. Nothing.</p> <p>3 Q. And do you have an opinion, based on your review of all</p> <p>4 of those medical records and all of the tests that were done</p> <p>5 on Mrs. Huskey in December, 2010, whether the scar tissue that</p> <p>6 you saw in March of 2014 was there in December of 2010?</p> <p>7 A. It was not.</p> <p>8 MS. JONES: Objection.</p> <p>9 THE COURT: Wait just a second.</p> <p>10 THE COURT: I will overrule it.</p> <p>11 BY MS. FITZPATRICK:</p> <p>12 Q. You can answer it.</p> <p>13 A. I did. I said, "It was not."</p> <p>14 Q. Okay. Thank you, Doctor.</p> <p>15 Now, going back to your opinions about the cause of</p> <p>16 Mrs. Huskey's injury, is the area where Mrs. Huskey is having</p> <p>17 her current pelvic pain distal or too far away from where the</p> <p>18 TVT-O device and surgeries were performed?</p> <p>19 A. No, it's not.</p> <p>20 Q. How close is it?</p> <p>21 A. I would say about -- from the -- well, actually, I</p> <p>22 shouldn't say that. About, I would say, two -- maybe two</p> <p>23 centimeters, the same size as my finger again.</p> <p>24 Q. Okay. And do you recall looking at Dr. -- I'm going to</p> <p>25 try this -- Ogunleye, I think it's Ogunleye's -- testimony in</p>

<p style="text-align: center;">Page 182</p> <p>1 this case?</p> <p>2 A. I did.</p> <p>3 Q. And do you recall that Dr. Ogunleye testified that</p> <p>4 Mrs. Huskey's pain was not where the TVT-O would be?</p> <p>5 A. Yes, I did see that.</p> <p>6 Q. Do you agree with Dr. Ogunleye in that statement?</p> <p>7 A. It's not in the course of where the TVT -- where the</p> <p>8 sling went, so I agree with that part.</p> <p>9 Q. Okay. And, in fact, at the time that Dr. Ogunleye had</p> <p>10 seen Mrs. Huskey, did she have any mesh remaining in her</p> <p>11 vagina at that point?</p> <p>12 A. Not in the vagina, I mean no, but, again, it could be --</p> <p>13 it could be in what I felt.</p> <p>14 Q. And did you also look at Dr. Mueller's records in this</p> <p>15 case?</p> <p>16 A. I did.</p> <p>17 Q. And Dr. Mueller had performed an ultra- -- pelvic</p> <p>18 ultrasound on Mrs. Huskey?</p> <p>19 A. Yes.</p> <p>20 Q. What do you recall about Dr. Mueller's conclusions about</p> <p>21 Mrs. Huskey's pelvic ultrasound?</p> <p>22 A. Well, she concluded that she didn't see any mesh there.</p> <p>23 Q. And did she also conclude that there was firmness on the</p> <p>24 left posterior vaginal wall?</p> <p>25 A. She did.</p>	<p style="text-align: center;">Page 184</p> <p>1 THE WITNESS: Perhaps I should have said it like</p> <p>2 that. Yes.</p> <p>3 BY MS. FITZPATRICK:</p> <p>4 Q. Now, Doctor, I want to turn your attention to the</p> <p>5 autologous fascial sling surgery that you had discussed</p> <p>6 before. And did we prepare a slide that gives an overview of</p> <p>7 what that surgery is?</p> <p>8 A. We did.</p> <p>9 MS. FITZPATRICK: I would like to publish that to the</p> <p>10 jury, Your Honor?</p> <p>11 THE COURT: All right.</p> <p>12 MS. JONES: No objection.</p> <p>13 (The document was published to the jury.)</p> <p>14 BY MS. FITZPATRICK:</p> <p>15 Q. Can you very briefly explain what the autologous fascial</p> <p>16 sling procedure to cure SUI is?</p> <p>17 A. Sure. It -- excuse me. It's -- all -- we're using the</p> <p>18 same word, "sling," for all of -- for both the TVT-O and the</p> <p>19 autologous fascial. The sling is a strip of material, and in</p> <p>20 this case, a strip that goes underneath the urethra, and in</p> <p>21 this case, that strip is made out of the patient's own natural</p> <p>22 tissue called fascia. The fascia is the lining of muscle, and</p> <p>23 it's obtained, if you look on your -- the upper left there, we</p> <p>24 make an incision -- it's actually much smaller than what you</p> <p>25 see here. The incision is about three of my finger breadths.</p>
<p style="text-align: center;">Page 183</p> <p>1 MS. JONES: Object to leading, Your Honor.</p> <p>2 THE COURT: It is. Sustained. The jury will</p> <p>3 disregard it.</p> <p>4 BY MS. FITZPATRICK:</p> <p>5 Q. Do you remember whether she had any other findings upon</p> <p>6 the pelvic examination?</p> <p>7 A. Yeah, she described feeling very much what I felt,</p> <p>8 the mass -- the tender mass on the posterior wall.</p> <p>9 Q. And at the time that she did that --</p> <p>10 A. Excuse me. The posterior lateral wall.</p> <p>11 Q. Okay. And at the time that she did that ultrasound, had</p> <p>12 the vaginal portion of the mesh been removed by Dr. Siddique?</p> <p>13 A. Yes.</p> <p>14 THE COURT: I'm going to stick in one of my questions</p> <p>15 here. So if she did an ultrasound, she -- the ultrasound</p> <p>16 could detect the mesh in the tissue; is that right?</p> <p>17 THE WITNESS: Well, it's possible -- I don't think it</p> <p>18 would detect such a small amount of mesh that I'm thinking of.</p> <p>19 I mean it will -- it should detect a broad band of sling, but</p> <p>20 that's not what I'm suspecting might be there. I'm thinking</p> <p>21 little slivers, and I don't think the ultrasound would detect</p> <p>22 that.</p> <p>23 THE COURT: Okay. My layman's summary of that is it</p> <p>24 could detect any sizeable piece of mesh but couldn't detect a</p> <p>25 sliver or small piece.</p>	<p style="text-align: center;">Page 185</p> <p>1 And through that incision, we cut out a piece -- a strip of</p> <p>2 fascia, which you see in the lower left, and then we close the</p> <p>3 incision in the fascia, and then we make a small incision,</p> <p>4 actually very similar to what Dr. Byrkit described for the</p> <p>5 first operation. We make a small incision in the vagina, and</p> <p>6 then we pass the sling from the abdominal part on one side,</p> <p>7 down into the vagina, around the urethra, and then back up</p> <p>8 into the abdomen on the other side, and then we tie it over</p> <p>9 the mid --in the middle.</p> <p>10 I don't do it exactly like this. I actually tie the</p> <p>11 two ends of the -- together, and then we close the wound. So</p> <p>12 it accomplishes the same kind of thing that is meant to</p> <p>13 accomplish with a -- with any kind of sling. It provides a</p> <p>14 hammock underneath the urethra.</p> <p>15 Q. And how long does it take to perform this operation?</p> <p>16 A. It takes me about an hour.</p> <p>17 Q. And how long do patients stay in the hospital after this</p> <p>18 operation?</p> <p>19 A. Nowadays, maybe 20 -- a total of maybe 24 hours.</p> <p>20 Q. And how quickly are patients able to return to normal</p> <p>21 activities after an autologous fascial sling procedure?</p> <p>22 A. Well, they're up and about the same day or the next day.</p> <p>23 I would say it takes a couple of weeks of -- before you're</p> <p>24 kind of feeling yourself. And then it's six weeks before I</p> <p>25 say that they can go back to full activities of full exercise,</p>

<p style="text-align: center;">Page 186</p> <p>1 but -- and stuff like that. But they can drive a car in a 2 week or a week or so.</p> <p>3 Q. Okay. And have you published articles concerning this 4 particular procedure?</p> <p>5 A. I have.</p> <p>6 Q. And have you taught other surgeons this procedure?</p> <p>7 A. I have.</p> <p>8 Q. And, based on your experience, training, research and 9 publications that you do, do you have an opinion on how 10 effective this procedure is in alleviating the symptoms of 11 SUI?</p> <p>12 A. Yes. I think it is as effective as any operation 13 anyplace. And the results -- the published literature would 14 support that.</p> <p>15 Q. I'm sorry, Doctor?</p> <p>16 A. And the published -- the peer review literature supports 17 that.</p> <p>18 Q. Okay. And how does the efficacy rate of the autologous 19 fascial sling, meaning how well it deals with SUI, compare 20 with the efficacy rate of transobturator midurethral slings?</p> <p>21 A. I think it's -- well, the published data shows that the 22 autologous sling is better in terms of efficacy, longer term 23 efficacy.</p> <p>24 Q. And is the autologous fascial sling considered a standard 25 of care for treatment of SUI in women?</p>	<p style="text-align: center;">Page 188</p> <p>1 talked about a little bit earlier?</p> <p>2 A. It does.</p> <p>3 Q. And can you tell me what you and your co-authors --</p> <p>4 MS. FITZPATRICK: Your Honor, I would like to move 5 21420 into evidence as a learned treatise.</p> <p>6 MS. JONES: I have no objection.</p> <p>7 THE COURT: Very well.</p> <p>8 (PLAINTIFFS' EXHIBIT P-21420 WAS RECEIVED IN EVIDENCE.)</p> <p>9 BY MS. FITZPATRICK:</p> <p>10 Q. And can you tell the jury, Doctor, what you and your 11 co-authors determined in this particular publication?</p> <p>12 A. Well, in specific reference to patients like Mrs. Huskey, 13 our success rate, not our cure rate, our success rate was 14 close to a hundred percent.</p> <p>15 Q. And what is the different between a success rate and a 16 cure rate?</p> <p>17 A. Cure rate means that you don't -- as we define it, it 18 means that you say you never leak -- we ask it on our 19 questionnaire -- you say that you never leak, and we have -- 20 you do what's called a pad test, where you wear a pad for 24 21 hours, and bring it back and we weigh it to see if there is 22 any leakage, and so that has to be tried, and the patient 23 answers a questionnaire saying that they never leak. So 24 that's a very -- very, very strict definition of "cure." And 25 in this paper -- and an improved -- it's a point system from</p>
<p style="text-align: center;">Page 187</p> <p>1 A. It is.</p> <p>2 Q. Now, you had mentioned some published literature.</p> <p>3 MS. FITZPATRICK: May I approach, Your Honor?</p> <p>4 THE COURT: You may.</p> <p>5 BY MS. FITZPATRICK:</p> <p>6 Q. And, Doctor, I have given you what's marked Plaintiffs' 7 Exhibit 21420. Do you see that?</p> <p>8 A. I do.</p> <p>9 Q. Okay. And can you identify this for the jury?</p> <p>10 A. It's entitled Pubovaginal Fascial Sling For All Types of 11 Stress Urinary Incontinence: Long-Term Analysis --</p> <p>12 Q. Okay. And what year was this published?</p> <p>13 A. 1998.</p> <p>14 Q. Okay. And can you tell the jury who the authors are on 15 this?</p> <p>16 A. David Chaikin, Jarrod Rosenthal, and myself.</p> <p>17 Q. And when you are talking in this -- actually, can you 18 tell me where it was published?</p> <p>19 A. Also in the Journal of Urology.</p> <p>20 Q. And when you and your co-authors were discussing the 21 pubovaginal fascial sling for all types of stress urinary 22 incontinence, did that include the type of stress urinary 23 incontinence that Mrs. Huskey has?</p> <p>24 A. It did.</p> <p>25 Q. And does it deal with those sphincteric deficits that we</p>	<p style="text-align: center;">Page 189</p> <p>1 zero to five.</p> <p>2 And improved is anything from a one, two or three, 3 which is different degrees of improvement. And the 4 improvement rate was a hundred percent.</p> <p>5 The cure rate, if I'm not mistaken, was in the high 60s 6 or 70 percent, which compares favorably with any other -- 7 anything else in the literature.</p> <p>8 Q. And does this support your opinions in this case that the 9 autologous fascial sling or the pubovaginal fascial sling is 10 an effective treatment for SUI in women?</p> <p>11 A. It does.</p> <p>12 Q. And I think you had mentioned that there were other 13 published articles on this topic. Is that right?</p> <p>14 A. Yes, there are many.</p> <p>15 MS. FITZPATRICK: May I approach, Your Honor?</p> <p>16 THE COURT: You may.</p> <p>17 BY MS. FITZPATRICK:</p> <p>18 Q. And, Doctor, I have given you what's marked as 19 plaintiffs' Exhibit 21379. Can you tell the jury what that 20 is?</p> <p>21 A. It's a -- it's an article entitled Clinical and Quality 22 of Life Outcomes After Autologous Fascial Slings, that's what 23 I just described, And Tension-Free Vaginal Tape, which is the 24 TVT we have been talking about, A Prospective Randomized Trial.</p>

<p style="text-align: center;">Page 190</p> <p>1 Q. Okay. Now, this deals with the TVT, not the TVT-O, 2 correct? 3 A. Correct. 4 Q. Are there any published articles comparing the TVT-O to 5 autologous slings? 6 A. I am not aware of any. 7 Q. And so what are the authors of this particular article -- 8 MS. FITZPATRICK: Actually, Your Honor, I would like 9 to move 21379 into evidence as a learned treatise. 10 MS. JONES: No objection as a learned treatise. 11 THE COURT: All right. 12 (PLAINTIFFS' EXHIBIT P-21379 WAS RECEIVED IN EVIDENCE.) 13 MS. FITZPATRICK: And if you can pull up the first 14 page of that, and highlight the conclusion. 15 (The document was published to the jury.) 16 BY MS. FITZPATRICK: 17 Q. Okay. Can you tell us what journal this was published 18 in? 19 A. The International Brazilian Journal of Urology. 20 Q. And is that a reputable journal? 21 A. It is. 22 Q. And when was it published? 23 A. In 2009. 2009. 24 Q. 2009. Okay. And the authors here concluded what? 25 A. Well, they concluded that the results were similar</p>	<p style="text-align: center;">Page 192</p> <p>1 patients had complications after the synthetic sling at two 2 years, two years after the surgery. 3 Q. Okay. And can you tell us where that was published? 4 A. In the American Journal of Obstetrics and Gynecology. 5 Q. And what year was that? 6 A. In 2011. 7 Q. Okay. 8 MS. FITZPATRICK: Your Honor, I would like to move 9 Plaintiffs' 21433 into evidence as a learned treatise. 10 MS. JONES: No objection, Your Honor. 11 THE COURT: All right. 12 (PLAINTIFFS' EXHIBIT P-21433 WAS RECEIVED IN EVIDENCE.) 13 BY MS. FITZPATRICK: 14 Q. And, Doctor, can you tell us what 20015 is? 15 A. 20015 is an article by the same authors -- or -- the same 16 authors entitled Five-Year Continence Rate Satisfaction and 17 Adverse Events of Burch Urethropexy in Fascial Sling Surgery 18 for Urinary Incontinence. In laymen's terms, it's looking at 19 how often patients, after the autologous sling that we were 20 just talking about, how often they had complications after 21 five years, and, also, how often patients with a Burch 22 operation, which is another kind of incontinence operation, 23 natural tissue operation, that we did not discuss so far. 24 Q. And did you help me, Doctor, prepare a slide that 25 summarized the findings from these researchers on the adverse</p>
<p style="text-align: center;">Page 191</p> <p>1 between the autologous fascial sling and the TVT except that 2 the operative time, how long it took, was shorter for the TVT. 3 Q. Okay. Can up summarize for the jury what that means in 4 relation to the opinions you've given in this case? 5 A. It supports what I said about the efficacy, about the 6 effectiveness of the autologous sling compared to the -- 7 compared to the TVT but not the TVT-O, that it's -- that they 8 are equally effective, but that the TVT had a shorter 9 operating time. 10 Q. Okay. And that would be -- 11 A. Takes less time to do the surgery. 12 Q. And was that the only distinction between them? 13 A. I think so. Let me see. 14 MS. FITZPATRICK: May I approach, Your Honor? 15 THE COURT: You may. 16 BY MS. FITZPATRICK: 17 Q. And, Doctor, I have given you two articles. One is 18 marked 21433, and the other is 20015. Is that right? 19 A. Yes. 20 Q. Can you tell the jury what Plaintiffs' Exhibit 21433 is? 21 A. Yes. That's a -- this is another study of slings 22 comparing -- this is looking at the -- the adverse events, 23 which are complications from the -- from slings. Looking at 24 adverse events in the trial of midurethral slings, which is -- 25 it's called -- yeah, that's -- it's looking at how often</p>	<p style="text-align: center;">Page 193</p> <p>1 events and the significant adverse events from the use of 2 synthetic slings and the adverse events and significant 3 adverse events from the the use of native tissue repairs? 4 A. I did. 5 MS. FITZPATRICK: I would like to publish that to the 6 jury. 7 MS. JONES: As a demonstrative, not to go to the 8 jury. It would be just as if Dr. Blaivas were getting up and 9 writing on the board, I have no objection, but -- 10 MS. FITZPATRICK: That's all I want, Your Honor. 11 THE COURT: All right. 12 MS. FITZPATRICK: Thank you. 13 Let's put that up on the screen. 14 (PLAINTIFFS' EXHIBIT P-20015 WAS RECEIVED IN EVIDENCE.) 15 (The document was published to the jury.) 16 BY MS. FITZPATRICK: 17 Q. Now, before we summarize what these researchers found, 18 let me ask you something. What is an AE? 19 A. I just told them. AE is an adverse event or a 20 complication. 21 Q. Okay. And what is an SAE? 22 A. A serious complication or a serious adverse event. 23 Q. So it's something that's more than the adverse events, 24 correct? 25 A. Correct.</p>